Filed pursuant to Rule 424(b)(3)
Registration No. 333-261853

PROSPECTUS

17,407,773 Common Shares

This prospectus relates to the potential offer and sale from time to time by the securityholders named in this prospectus (the "Holders") of up to 17,407,773 of our common shares, $0.0000000341740141 par value per share (the "Common Shares"), issued pursuant to the Agreement and Plan of Merger, dated as of February 2, 2021, between Roivant Sciences Ltd., Silicon Therapeutics LLC, Silicon Insite, Inc. and Silicon TX China. Of the 17,407,773 Common Shares registered hereby (i) 11,059,716 Common Shares were issued prior to the closing of the Business Combination (as defined herein) and are therefore subject to lock-up through the date six months from the closing of the Business Combination, and (ii) 6,348,057 Common Shares were issued following the closing of the Business Combination and will therefore be freely tradeable following the effectiveness of the Registration Statement of which this Prospectus forms a part.

The Holders may offer, sell or distribute all or a portion of the Common Shares hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any proceeds from the sale of Common Shares by the Holders pursuant to this prospectus. We will bear all costs, expenses and fees in connection with the registration of these Common Shares, including with regard to compliance with state securities or "blue sky" laws. The timing and amount of any sale are within the sole discretion of the Holders. The Holders and any underwriters, dealers or agents that participate in distribution of the Common Shares may be deemed to be underwriters, and any profit on sale of the Common Shares by them and any discounts, commissions or concessions received by any underwriter, dealer or agent may be deemed to be underwriting discounts and commissions under the Securities Act. There can be no assurances that the Holders will sell any or all of the Common Shares offered under this prospectus. The Holders will bear all commissions and discounts, if any, attributable to their sale of Common Shares. See "Plan of Distribution."

Our Common Shares are listed on The Nasdaq Global Market under the symbol "ROIV." On January 3, 2022, the last reported sale price of our Common Shares was $9.91 per Common Share.

We are an "emerging growth company" under federal securities laws and are subject to reduced public company reporting requirements. Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 5 of this prospectus, and under similar headings in any amendment or supplements to this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 4, 2022.

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the "SEC") using the "shelf" registration process. Under this shelf registration process, the Holders may, from time to time, sell the securities offered by them described in this prospectus. We will not receive any proceeds from the sale by such Holders of the securities offered by them described in this prospectus.

Neither we nor the Holders have authorized anyone to provide you with any information other than that provided in this prospectus, as well as any information incorporated by reference into this prospectus and any applicable prospectus supplement. Neither we nor the Holders can provide any assurance as to the reliability of any other information that others may give you. Neither we nor the Holders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus, any applicable prospectus supplement or any documents incorporated by reference is accurate as of any date other than the date of the applicable document. Since the respective dates of this prospectus and the documents incorporated by reference into this prospectus, our business, financial condition, results of operations and prospects may have changed.

We may also provide a prospectus supplement or post-effective amendment to the registration statement to add information to, or update or change information contained in, this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendment to the registration statement together with the additional information to which we refer you in the sections of this prospectus entitled "*Where You Can Find More Information*."

Unless the context indicates otherwise, references in this prospectus to the "Company," "Roivant," "we," "us," "our" and similar terms refer to Roivant Sciences Ltd., a Bermuda exempted limited company, and its consolidated subsidiaries. Note that references in this prospectus to Roivant's development pipeline, product candidate pipeline or discovery stage pipeline may omit certain programs, product candidates or assets that are not material to Roivant individually or in the aggregate.

FREQUENTLY USED TERMS

"Business Combination" means the transactions contemplated by the Business Combination Agreement, pursuant to which Merger Sub merged with and into MAAC, with MAAC surviving the merger.

"Business Combination Agreement" means the business combination agreement, dated as of May 1, 2021, as amended, by and among Roivant, MAAC and Merger Sub.

"Common Shares" means each Common Share of Roivant, par value $0.0000000341740141 per share.

"Effective Time" means the effective time of the closing of the Business Combination.

"MAAC" means (x) prior to the Business Combination, Montes Archimedes Acquisition Corp., a Delaware corporation and (y) from and after the Business Combination, Roivant Rhine Holdings, Inc.

"MAAC Class A Shares" means each share of Class A common stock of MAAC, par value $0.0001 per share.

"MAAC Class B Shares" means each share of Class B common stock of MAAC, par value $0.0001 per share.

"MAAC Shares" means, collectively, the MAAC Class A Shares and the MAAC Class B Shares.

"MAAC Sponsor" means Patient Square Capital LLC.

"MAAC Warrant" means each whole warrant of MAAC entitling the holder to purchase one MAAC Class A Share per warrant at a price of $11.50 per share.

"Merger Sub" means Rhine Merger Sub, Inc., a Delaware corporation.

"Myovant Top-Up Shares" means common shares of Myovant Sciences Ltd. ("Myovant") subject to the Share Return Agreement, dated as of December 27, 2019, between Roivant and Sumitomo Dainippon Pharma Co., Ltd. For more information, see Roivant's Schedule 13D with respect to Myovant filed with the SEC on December 31, 2019.

"PIPE Financing" means the sale and issuance to the PIPE Investors of an aggregate of 22,000,000 MAAC Class A Shares at a purchase price of $10.00 per share, for aggregate gross proceeds of $220,000,000.

"PIPE Investors" means those certain institutional and accredited investors that entered into the Subscription Agreements in connection with the PIPE Financing.

"Private Placement Warrants" means the 10,214,365 warrants sold simultaneously with the closing of the initial public offering (including through exercise of the over-allotment option) of MAAC at a price of $1.00 to the MAAC Sponsor and then converted into warrants to purchase Common Shares in connection with the closing of the Business Combination.

"Public Warrants" means the 20,535,912 warrants sold simultaneously with the closing of the initial public offering of MAAC and then converted into warrants to purchase Common Shares in connection with the closing of the Business Combination. After giving effect to rounding to eliminate fractional warrants in connection with the closing of the Business Combination, there were 20,535,896 Public Warrants outstanding as of December 1, 2021.

"Public Vants" means Arbutus Biopharma Corp., Immunovant, Inc. and Sio Gene Therapies, Inc.

"Sponsor Support Agreement" means the agreement, dated as of May 1, 2021, as amended by Amendment No. 1, dated as of June 9, 2021 and Amendment No. 2, dated as of September 30, 2021, pursuant to which the MAAC Sponsor agreed to undertake certain actions in support of the Business Combination, including, but not limited to, delivering a voting proxy pursuant to which the MAAC Sponsor voted in favor of the proposals presented for approval herein.

"Subscription Agreements" means the subscription agreements entered into by the PIPE Investors providing for the purchase by the PIPE Investors at the Effective Time of an aggregate of 22,000,000 MAAC Class A Shares at a price per share of $10.00.

"Roivant" means Roivant Sciences Ltd., a Bermuda exempted limited company, together with its consolidated subsidiaries, as context requires.

"Warrants" means, collectively, the Private Placement Warrants and the Public Warrants.

"Transactions" means the Business Combination and the other transactions contemplated by the Business Combination Agreement.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on us taking into account information currently available to us. There can be no assurance that future developments affecting us will be those that we have anticipated. Should one or more of these risks or uncertainties materialize, they could cause our actual results to differ materially from the forward-looking statements. Some factors that could cause actual results to differ include, but are not limited to risk associated with:

- our limited operating history and risks involved in biopharmaceutical product development;
- the fact that we will likely incur significant operating losses for the foreseeable future;
- the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) on our business (including our clinical trials and pre-clinical studies), operations and financial condition and results;
- our ability to acquire, in-license or discover new product candidates;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- clinical trials and pre-clinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- the unproven nature of our approach to the discovery and development of product candidates from our targeted protein degradation platform;
- the novelty, complexity and difficulty of manufacturing certain of our product candidates, including any manufacturing problems that result in delays in development or commercialization of our product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials and/or clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- changes in interim, top-line and/or preliminary data from our clinical trials changing as more data becoming available or being delayed due to audit and verification process;
- changes in product manufacturing or formulation that could lead to the incurrence of costs or delays;
- the failure of any third party we contract with to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable requirements;
- the fact that obtaining approvals for new drugs is a lengthy, extensive, expensive and unpredictable process that may end with our inability to obtain regulatory approval by the FDA or other regulatory agencies in other jurisdictions;

- the failure of our clinical trials to demonstrate substantial evidence of the safety and efficacy of product candidates, including, but not limited to, scenarios in which our product candidates may cause adverse effects that could delay regulatory approval, discontinue clinical trials, limit the scope of approval or generally result in negative media coverage of us;
- our inability to obtain regulatory approval for a product candidate in certain jurisdictions, even if we are able to obtain approval in certain other jurisdictions;
- our ability to effectively manage growth and to attract and retain key personnel;
- any business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally;
- our ability to obtain and maintain patent and other intellectual property protection for our technology and product candidates;
- the inadequacy of patent terms and their scope to protect our competitive position;
- the failure to issue (or the threatening of their breadth or strength of protection) or provide meaningful exclusivity for our product candidates or any future product candidate of our patent applications that we hold or have in-licensed;
- the fact that we do not currently and may not in the future own or license any issued composition of matter patents covering certain of our product candidates and our inability to be certain that any of our other issued patents will provide adequate protection for such product candidates;
- the fact that our largest shareholders (and certain members of our management team) own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval;
- the outcome of any legal proceedings that may be instituted against us in connection with the Business Combination and related transactions;
- changes in applicable laws or regulations;
- the possibility that we may be adversely affected by other economic, business and/or competitive factors; and
- other risks and uncertainties, including those described under the heading “Risk Factors.”

These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

SUMMARY OF THE PROSPECTUS

This summary highlights selected information appearing elsewhere in this prospectus or the documents incorporated by reference herein. Because it is a summary, it may not contain all of the information that may be important to you. To understand this offering fully, you should read this entire prospectus, the registration statement of which this prospectus is a part and the documents incorporated by reference herein carefully, including the information set forth under the heading "Risk Factors" and our financial statements.

Overview of the Company

We are building the next-generation "big pharma" company, organized to harness modern technologies and the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity.

We are a diverse team of experienced drug developers, scientists, physicians, company builders, data scientists and engineers, biopharma investors, physicists and business development professionals dedicated to improving the lives of patients. At Roivant, we combine our team's extensive experience and multi-disciplinary expertise with innovative technologies to identify and advance potentially transformative medicines.

We deploy a hypothesis-driven approach to identify novel or clinically-validated targets and biological pathways in areas of high unmet medical need. We then seek to acquire, in-license or discover promising drug candidates against those targets or pathways. Our small molecule discovery engine is powered by a unique combination of leading computational physics and machine learning capabilities for *in silico* drug design.

We develop drug candidates in subsidiary companies we call "Vants" with a distinct approach to sourcing talent, aligning incentives and deploying technology. Each of our Vant teams is built with deep relevant expertise to promote successful execution of our development strategy. Our Vants continue to benefit from the support of the Roivant platform and technologies that are built to address inefficiencies in the drug discovery, development and commercialization process.

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology, hematology and oncology, and modalities, including biologics, topicals, gene therapies and bifunctional small molecules. We currently have 14 Vants and, together, we are advancing a deep and diversified pipeline of over 30 drug candidates. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately $940 million in the Public Vants as of September 30, 2021 (inclusive of the value of the Myovant Top-Up Shares). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

- conducted nine international Phase 3 trials, the last eight of which have been successful;
- consummated a $3 billion upfront partnership with Sumitomo Dainippon Pharma ("Sumitomo");
- developed four drugs that received FDA approval after their transfer to Sumitomo;
- built a pipeline of over 30 drug candidates ranging from early discovery to registration;
- launched Roivant Discovery, our small molecule discovery engine comprising advanced computational physics and machine learning capabilities, integrated with an in-house wet lab facility; and

- created innovative software tools to optimize each stage of the drug discovery, development and commercialization process.

On October 9, 2020, MAAC completed its initial public offering of MAAC Units, consisting of one MAAC Class A Share and one-half of one MAAC Warrant, with each unit consisting of one share of MAAC's Class A common stock and one-half of one MAAC Warrant, with each whole MAAC Warrant entitling the holder thereof to purchase one share of MAAC's Class A common stock at a price of $11.50 per share. On September 30, 2021, Merger Sub merged with and into MAAC, with MAAC continuing as the surviving company. As a result of such merger and the other Transactions, MAAC became a direct, wholly-owned subsidiary of Roivant under the name "Roivant Rhine Holdings, Inc."

Roivant's principal executive office is located at Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, United Kingdom.

Summary Risk Factors

An investment in our Common Shares involves substantial risk. The occurrence of one or more of the events or circumstances described in the section of this prospectus entitled "Risk Factors," alone or in combination with other events or circumstances, may have a material adverse effect on our business, cash flows, financial condition and results of operations. Important factors and risks that could cause actual results to differ materially from those in the forward-looking statements include, among others, the following:

Risks Related to Our Business and Industry

- Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development may make it difficult for us to execute on our business model and for you to assess our future viability.
- We will likely incur significant operating losses for the foreseeable future and may never achieve or maintain profitability.
- The ongoing global pandemic resulting from the outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and pre-clinical studies.
- We may not be successful in our efforts to acquire, in-license or discover new product candidates.
- Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment approaches, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.
- We face risks associated with the Vant structure.
- Clinical trials and pre-clinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or pre-clinical studies on the expected timelines, if at all.
- Our approach to the discovery and development of product candidates from our targeted protein degradation platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from this platform.
- Certain of our product candidates, including our gene therapy product candidates, are novel, complex and difficult to manufacture.

- Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulator may delay, limit or deny approval.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.
- We depend on the knowledge and skills of our senior leaders, and may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- Changes in funding for, or disruptions to the operations of, the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.
- We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt operations.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If the patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs.
- Patent terms and their scope may be inadequate to protect our competitive position on current and future product candidates for an adequate amount of time.

Risks Related to Our Securities, Our Jurisdiction of Incorporation and Certain Tax Matters

- The listing of our securities on Nasdaq did not benefit from the process undertaken in connection with an underwritten initial public offering.
- If our performance does not meet market expectations, the price of our securities may decline.
- We have and will continue to incur increased costs as a result of operating as a public company and our management has and will continue to devote a substantial amount of time to new compliance initiatives.
- Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.
- Anti-takeover provisions in our memorandum of association, bye-laws and Bermuda law could delay or prevent a change in control, limit the price investors may be willing to pay in the future for our Common Shares and could entrench management.
- Our largest shareholders and certain members of our management own a significant percentage of our Common Shares and will be able to exert significant control over matters subject to shareholder approval.

THE OFFERING

Issuer	Roivant Sciences Ltd.
Common Shares offered by the Holders	Up to 17,407,773 Common Shares.
Use of Proceeds	We will not receive any proceeds from any sale of Common Shares by the Holders. See "Use of Proceeds."
Market for Common Shares	The Common Shares are currently traded on The Nasdaq Global Market under the symbol "ROIV."
Risk Factors	See "*Risk Factors*" and other information included in this prospectus for a discussion of factors you should consider before investing in our securities.

For additional information concerning the offering, see "Plan of Distribution."

RISK FACTORS

Our business involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our condensed consolidated financial statements and the related notes appearing elsewhere in this prospectus, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by us and our majority-controlled subsidiary, Immunovant, Inc. ("Immunovant"), with the SEC. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, prospects, results of operations, financial condition and cash flows. If any such events were to happen, the trading shares of our Common Shares could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

Risks Related to Our Financial Position and Strategy

Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development may make it difficult for us to execute on our business model and for you to assess our future viability. We have never generated product revenue from the commercialization of our drug product candidates, and there is no guarantee that we will do so in the future.

We are a biopharmaceutical and healthcare technology company with a limited operating history upon which you can evaluate our business and prospects. We were formed in April 2014, and our operations to date have been limited to acquiring or in-licensing product candidates or developing technologies for the discovery, development, and commercialization of product candidates, starting or acquiring subsidiary businesses, which we refer to as the Vants, in which to house those product candidates or technologies, and hiring management teams to operate the Vants and oversee the development of our product candidates and technologies.

Our ability to execute on our business model and generate revenues depends on a number of factors including our ability to:

- identify new acquisition or in-licensing opportunities;
- successfully identify new product candidates through our computational discovery and targeted protein degradation platforms and advance those product candidates into pre-clinical studies and clinical trials;
- successfully complete ongoing pre-clinical studies and clinical trials and obtain regulatory approvals for our current and future product candidates;
- successfully market our healthcare technology products and services;
- raise additional funds when needed and on terms acceptable to us;
- attract and retain experienced management and advisory teams;
- add operational, financial and management information systems and personnel, including personnel to support clinical, pre-clinical manufacturing and planned future commercialization efforts and operations;
- launch commercial sales of product candidates, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of product candidates manufactured at acceptable cost and quality levels and in compliance with the U.S. Food and Drug Administration (the "FDA") and other regulatory requirements;
- set acceptable prices for product candidates and obtain coverage and adequate reimbursement from third-party payors;

- achieve market acceptance of product candidates in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

If we cannot successfully execute any one of the foregoing, our business may not succeed and the price of our Common Shares may be negatively impacted.

Biopharmaceutical product development, which represents the core of our business model, is a highly speculative undertaking and involves a significant degree of risk. Our product candidates will require substantial development time – including extensive clinical, and in some cases pre-clinical, research and development – and resources before we would be able to apply for or receive applicable regulatory approvals and begin generating revenue from product sales.

We have not yet demonstrated an ability to successfully acquire regulatory clearance or approval, develop or manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful biopharmaceutical product commercialization. We have generated minimal revenues to date, and no revenues from the commercialization of our drug product candidates. Consequently, we have limited operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical product candidates.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to predict the timing or amount of increased expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our product candidates that we may identify. Even if a product is approved for commercial sale, we could incur significant costs associated with the commercial launch of any such product.

We may never be able to develop or commercialize a marketable drug or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price, the strength and term of patent exclusivity for the product, the competitive landscape of the product market, and whether we own the commercial rights for that territory. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, expand our pipeline, market our product candidates, if approved, and pursue or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

We will likely incur significant operating losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. None of our current product candidates has received marketing approval anywhere in the world and we have not generated any product revenues from the commercial sale of our biopharmaceutical products. We cannot estimate with precision the extent of our future losses. We may never generate product revenue from the commercial sales of our product candidates or achieve profitability.

We expect to continue to incur substantial operating losses through the projected commercialization of our product candidates. Our ability to generate product revenue and achieve profitability is dependent on the ability to complete the development of our product candidates, obtain necessary regulatory approvals and manufacture and successfully market product candidates alone or in collaboration with others.

If we do successfully obtain regulatory approval to market product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for product candidates and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than expected, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. We cannot assure you that we will be profitable even if we successfully commercialize our product candidates.

The ongoing global pandemic resulting from the outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and pre-clinical studies.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, emerged. COVID-19 has since spread globally, including to the countries in which we and our other business partners conduct business. Governments in affected regions have implemented, and may continue to implement or re-implement, safety precautions, including quarantines, travel restrictions, business closures, cancellations of public gatherings and other measures they deem necessary. Like many other organizations and individuals, we and our employees have taken additional steps to avoid or reduce infection, including limiting travel and implementing remote work arrangements. We will continue to actively monitor the situation and may take further actions that could alter our business operations as may be required by national, state or local authorities, or that we determine are in the best interests of our employees and shareholders.

As a result of the COVID-19 pandemic and policy responses to it, in April and May 2020 we initially observed a decrease in both patient screening and patient enrollment in certain of our ongoing clinical trials. Patient screening and the number of patients eligible for enrollment in our clinical trials has since returned to expected levels. However, some of our development programs have been delayed. Together with our investigators and clinical sites, we continue to assess the impact of the coronavirus pandemic on enrollment and the ability to maintain patients enrolled in our clinical trials and the corresponding impact on the timing of the completion of our ongoing clinical trials. We have experienced, or may in the future experience, disruptions as a result of COVID-19 or future pandemics that severely impact our business, clinical trials and pre-clinical studies, including:

- delays or difficulties in enrolling patients in our clinical trials, and the consequences of such delays or difficulties, including terminating clinical trials prematurely;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments due to unforeseen circumstances at contract research organizations (“CROs”), and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or

interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA and comparable non-U.S. regulatory agencies, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical studies, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- other disruptions to our business generally, including from the transition to remote working for the majority of our employees and the implementation of new health and safety requirements for our employees; and
- waiver or suspension of patent or other intellectual property rights.

These and other factors arising from the COVID-19 pandemic, including risks relating to the emergence of the delta variant and other new variants, the efficacy and availability of vaccines and rates of vaccination, the pandemic worsening in countries that are already afflicted with COVID-19 or the COVID-19 pandemic continuing to spread to additional countries or returning to countries where the pandemic has been partially contained, could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

We are continuing to monitor potential delays or other impacts on our business, our clinical trials, healthcare systems and the global economy as a whole. These effects could have a material impact on our business, operations and financial results.

To the extent the COVID-19 pandemic adversely affects our business, operations and financial results, it may also have the effect of heightening many of the other risks described elsewhere, such as those relating to our clinical development operations, the supply chain for our ongoing and planned clinical trials and our ability to seek and receive regulatory approvals for our product candidates.

We may not be successful in our efforts to acquire, in-license or discover new product candidates.

The success of our business is highly dependent on our ability to successfully identify new product candidates, whether through acquisitions or in-licensing transactions, or through our internal discovery capabilities. Our acquisition and in-licensing efforts focus on identifying assets in development by third parties across a diverse range of therapeutic areas that, in our view, are underutilized or undervalued. Our strategy often entails designing low-cost studies that result in quick “go/no-go” decisions when deciding whether or how to proceed with future development for a given asset, once acquired. We may decide to proceed with the development of a drug candidate on this basis and later determine that the more costly and time intensive trials do not support the initial value the product was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

Our drug discovery efforts are centered on our targeted protein degradation platform and our computational discovery technology. As a company we have relatively limited experience in drug discovery generally, with

targeted protein degradation as an approach to target inhibition and with computational discovery as a technology. Our future success depends, in part, on our ability to successfully use targeted protein degradation and computational discovery technology to identify promising new product candidates.

Very few small molecule product candidates using targeted protein degradation, such as the product candidates which may be generated by our targeted protein degradation platform, have been tested in humans and none has been approved in the United States or Europe. The data underlying the feasibility of developing therapeutic products based on protein degradation technology is both preliminary and limited. We have not yet succeeded and may not succeed in advancing any product candidates developed using our targeted protein degradation platform into clinical trials, demonstrating the efficacy and safety of such product candidates or obtain marketing approval thereafter. As a result, it is difficult to predict the time and cost of protein degrader product candidate development and we cannot predict whether the application of our targeted protein degradation platform will result in the development and marketing approval of any products. Any problems we experience in the future related to this platform or any of our related development programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any internally discovered product candidates we may develop on a timely or profitable basis, if at all.

Although we believe that our computational discovery platform has the potential to identify more promising molecules than traditional research methods and to accelerate drug discovery efforts, our focus on using our platform technology to discover and design molecules with therapeutic potential may not result in the discovery and development of commercially viable products for us. Computational discovery is a relatively new approach to drug development. As an organization, we have not yet developed any product candidates using this technology that have advanced into clinical trials and we may fail to identify potential product candidates for clinical development. Even if we are able to advance product candidates identified through our computational discovery platform into clinical trials, those trials may not be successful in demonstrating the efficacy and safety of such product candidates and, as a result, we may not be able to obtain regulatory approvals for those product candidates.

Any such failure to in-license or acquire new product candidates from third parties, or to discover new product candidates using our targeted protein degradation or computational discovery platforms would have a material adverse effect on our business, financial condition, results of operations and prospects.

Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment approaches, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and management resources. As a result, we may forego or delay pursuit of opportunities with potential target indications or product candidates that later prove to have greater commercial potential than our current and planned development programs and product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be required to relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Additionally, we may pursue additional in-licenses or acquisitions of product candidates or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual

acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We face risks associated with the Vant structure.

We develop our product candidates in the Vants, which operate similarly to independent biopharmaceutical companies. While we believe that there are significant competitive advantages to this structure, as compared to traditional pharmaceutical companies or smaller biopharma companies, the Vant structure also poses certain risks for our business.

Operating the Vants independently, rather than under a centralized, consolidated management team, may result in increased costs at the Vants, as certain functions or processes, including clinical and non-clinical personnel, business development, finance, accounting, human resources and legal functions, are replicated across the Vants. There may also be certain start-up costs, associated with the establishment of a new Vant or integration of a newly acquired business into a Vant, which are greater under the Vant model than they would be under a centralized model. The use of the Vant model may also entail increased costs for us, including the time and expenses associated with hiring Vant CEOs and management teams, overseeing Vant equity incentive arrangements and managing compliance-related risks, including the internal controls, reporting systems and procedures necessary for us to operate as a public company. We may also be exposed to increased "key employee" risks, in the event a Vant CEO were to depart, including the loss of other senior Vant personnel, potentially resulting in significant delays to the development programs at the Vant. These increased expenses, complexities and other challenges may make using and scaling the Vant model more challenging and costly than it would be for a traditional pharmaceutical company to both operate and expand the number of product candidates under development, which could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects. This decentralized model could also make compliance with applicable laws and regulations more challenging to monitor and may expose us to increased costs that could, in turn, harm our business, financial condition, results of operations or prospects.

In addition, a single or limited number of the Vants may, now or in the future, comprise a large proportion of our value. Similarly, a large proportion of our consolidated revenues may in the future be derived from one or a small number of Vants. Any adverse development at those Vants, including the termination of a key license agreement or other loss of the intellectual property underlying a product candidate or the failure of a clinical trial for a product candidate under development at the Vant, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects.

We manage the Vants in part through our designees who serve on the Vant boards of directors. In their capacities as directors, those individuals owe fiduciary duties to the Vants and their shareholders under applicable law, which may at times require them to take actions that are not directly in our interest. To the extent any such actions have an adverse effect on the value of our ownership interest in the Vant, it could further adversely impact our consolidated business, financial condition, results of operations or prospects.

Our business may suffer reputational harm due to failures of our product candidates.

The failure of any of our product candidates could have a lasting negative impact on our reputation, which could, in turn, impact our ability to successfully enter into future licensing arrangements or other transactions with potential counterparties, raise future capital or attract key personnel to join us. As a result, our business and prospects would be materially harmed and our results of operations and financial condition would likely suffer materially.

We face risks associated with potential future payments related to our product candidates.

Our model for asset in-licensing transactions typically involves a low upfront payment combined with milestone and royalty payments contingent upon the achievement of certain future development and commercial events. These arrangements generally involve a payment or payments upon certain regulatory milestones, including regulatory approval, and then upon achieving specified levels of sales, with ongoing royalty payments which can extend for up to the life of a product. These payments may become due before a product is generating revenues, in which case we may not have sufficient funds available to meet our obligations. If this were to occur, we would default on our payment obligations and could face penalties, delays in development or reputational damage. Even if a product is commercialized and generating revenue, payments could become due that are so large that the investment is not profitable or is less profitable than anticipated. For example, this could occur if at the time of the initial investment, we overestimated the value of the product and agreed to a payment schedule using these inflated estimates. If we are unable to make milestone and royalty payments related to our product candidates when due, our business and prospects could suffer.

Our investment strategy and future growth relies on a number of assumptions, some or all which may not be realized.

Our investment strategy and plans for future growth rely on a number of assumptions, including, in the case of our biopharmaceutical product candidates, assumptions related to adoption of a particular therapy, incidence of an indication, use of a product candidate versus competitor therapies and size of patient populations. Some or all of these assumptions may be incorrect. We cannot accurately predict whether our product candidates will achieve significant market acceptance in line with these assumptions or whether there will be a market for our product candidates that reaches that which is anticipated. If any of these assumptions are incorrect or overstated, our results and future prospects will be materially and adversely affected.

If we enter into acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring new product candidates, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our or our subsidiaries’ equity securities which would result in dilution to our shareholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates, intellectual property, and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

We face risks associated with our ongoing strategic alliance with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo"), as well as other acquisitions, partnerships, alliances or strategic transactions we may undertake in the future.

In December 2019, we and Sumitomo completed various transactions in connection with the formation of a strategic alliance between the companies, including (i) Sumitomo indirectly acquiring from us our controlling equity interests in five affiliates, (ii) our granting Sumitomo options to purchase, subject to certain exceptions, our existing equity interests in six other privately-held affiliates of ours, (iii) our granting Sumitomo access to key elements of our proprietary technology platforms and (iv) issuing our Common Shares to Sumitomo. In exchange, Sumitomo made a $3.0 billion upfront cash payment to us upon the closing of the transactions.

We face a number of risks in connection with our transactions with Sumitomo, including, but not limited to:

- diversion of management time and focus away from operating our business;
- reliance on certain employees of the alliance with Sumitomo who will continue to provide key services for us, including information technology services;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from these transactions;
- risks arising from technological and data platforms shared between us and the alliance with Sumitomo, such as DrugOme®, including data or other security breaches at Sumitomo or its affiliates that could, in turn, impact us, or disputes over ownership of intellectual property between us and the alliance with Sumitomo, which could impact our access to those platforms;
- non-competition obligations arising from the formation of the alliance with Sumitomo;
- coordination of research and development efforts; and
- litigation or other claims, including claims from terminated employees, customers, former shareholders or other third parties.

We may also face similar risks in connection with any other mergers, acquisitions, divestitures or strategic alliances that we have undertaken in the past or may undertake in the future, including our acquisition of Oncopia Therapeutics, which closed in November 2020, and of Silicon Therapeutics, which closed in March 2021. If we acquire businesses with promising technologies, we may not be able to realize the benefits of acquiring such businesses, including any anticipated synergies between the acquired business and our existing business, if we are unable to successfully integrate them with our existing operations, technology and company culture.

In addition, any such mergers, acquisitions, divestitures or strategic alliances may be complex, time consuming and expensive to execute and may be subject to regulatory requirements that could impact our business. There can be no guarantee that we will be able to successfully consummate such acquisitions or other transactions, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket costs.

If any acquisitions or other transactions are not completed for any reason, we may incur significant costs and the market price of our Common Shares may decline. In addition, even if an acquisition is consummated, the integration of the acquired business, product or other assets into our Company may be complex and time-consuming, and we may not achieve the anticipated benefits, cost-savings or growth opportunities we expect. Potential difficulties that may be encountered in the integration process include the following: integrating

personnel, operations and systems; coordinating geographically dispersed organizations; distracting management and employees from current operations; maintaining the existing business relationships of the acquired company; and managing inefficiencies associated with integrating the operations of the Company and the acquired business, product or other assets. For biopharmaceutical businesses we have acquired or may acquire in the future, or alliances or joint ventures in the biopharmaceutical industry, we may encounter numerous difficulties in developing, manufacturing and marketing any new drugs related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, alliance or partnership, we will achieve the expected synergies to justify the transaction.

Our failure to address these risks or other problems encountered in connection with the strategic alliance with Sumitomo, or other past or future acquisitions, partnerships or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, incur unanticipated liabilities and harm our business generally. There is also a risk that current or future acquisitions will result in the shareholder litigation, incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

If we obtain a controlling interest in additional companies in the future, it could adversely affect our operating results and the value of our Common Shares, thereby disrupting our business.

As part of our strategy, we expect to form and invest in additional wholly-owned and majority-owned subsidiaries. Investments in our existing and any future subsidiaries involve numerous risks, including, but not necessarily limited to, risks related to:

- conducting research and development activities in new therapeutic areas or treatment approaches in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- actual or potential conflicts among new and existing Vants to the extent they have overlapping or competing areas of focus or pipeline products;
- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our biopharmaceutical product candidates, as well as to advance the development of our healthcare technologies. Because the length of time and activities associated with successful development of our biopharmaceutical product candidates is highly uncertain, and due to the inherent challenges and uncertainties associated with the development of novel healthcare technologies, we are unable to estimate with certainty the actual funds we will require to execute on our strategy.

Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- with respect to our biopharmaceutical product candidates:
  - the cost and timing of newly launched product candidates or Vants;
  - the initiation, timing, progress, costs and results of pre-clinical studies and clinical trials for our product candidates;
  - the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable non-U.S. regulatory authorities globally;
  - the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
  - the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
  - the cost and timing of completion of pre-clinical, clinical and commercial manufacturing activities;
  - the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our product candidates on our own;
  - the initiation, progress, timing and results of our commercialization of our product candidate, if approved for commercial sale; and
  - other costs associated with preparing the commercial launch of our product candidates;
- for our healthcare and drug discovery technologies:
  - the costs related to hiring and retaining employees with the expertise necessary to manage these technologies;
  - investments in wet labs, computational resources and other facilities; and
  - the costs needed to update, maintain and improve these technologies and the infrastructure underlying these technologies, including with respect to data protection and cybersecurity.

We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of any product candidate, delay the launch or expansion of a given healthcare technology product or potentially discontinue our operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our business. Because of the numerous risks and uncertainties associated with our business, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current product development programs and technology products.

We expect that significant additional capital will be needed in the future to continue our planned operations, including with respect to fulfilling our and the Vants' human resources needs, which may be costly. Until such time, if ever, that we can generate substantial revenues, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations both at our parent and at certain affiliates. To the extent that we raise additional capital by issuing equity securities at the parent or subsidiary level, our existing shareholders' ownership, or our ownership in our subsidiaries, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise

additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. The foregoing restrictions associated with potential sources of additional capital may make it more difficult for us to raise additional capital or to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, if and when we require it, our ability to grow or support our business and to respond to business challenges could be significantly limited.

Risks Related to the Development of Our Product Candidates

Clinical trials and pre-clinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or pre-clinical studies on the expected timelines, if at all.

Our biopharmaceutical product candidates are in clinical development or pre-clinical studies and will require, as applicable, extensive clinical testing before a New Drug Application ("NDA") or other similar application for regulatory approval, such as a Biologics License Application ("BLA") or an application for marketing authorization in the European Union ("EU") or United Kingdom ("UK"), may be submitted, or extensive pre-clinical testing before an Investigational New Drug application ("IND") or an application for authorization for the conduct of a clinical trial in the EU or UK may be submitted. We cannot provide you any assurance that we will submit an IND, NDA or other similar application for regulatory approval for our product candidates within projected timeframes or whether any such application will be approved by the relevant regulatory authorities.

Clinical trials and pre-clinical studies are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA, an institutional review board ("IRB"), an Ethics Committee ("EC") or other regulatory authorities may not agree with the proposed analysis plans or trial design for the clinical trials of our product candidates, and during any such review, may identify unexpected efficacy or safety concerns, which may delay the effective date of an IND or approval of an NDA or similar application. The FDA, the European Medicines Agency ("EMA") or the European Commission or other relevant regulatory authority may also find that the benefits of any product candidate in any applicable indication do not outweigh its risks in a manner sufficient to grant regulatory approval.

The FDA or other regulatory authorities may also not agree with the scope of our proposed investigational plan. For example, they may find that our proposed development program is not sufficient to support a marketing authorization application, or that the proposed indication is considered to be too broad. Moreover, the FDA or other regulatory authorities may also refuse or impose certain restrictions on our reliance on data supporting our marketing authorization application should such data originate from studies outside of the relevant jurisdiction or be affected by regulatory non-compliance, including issues of data integrity. In each case, this could delay the clinical development and authorization timeline for a given product candidate.

Failures can occur at any stage of clinical trials or pre-clinical studies, and we could encounter problems that cause us to abandon or repeat clinical trials or pre-clinical studies. In addition, results from clinical trials or pre-clinical studies may require further evaluation, delaying the next stage of development or submission of an IND or an NDA or similar application. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in pre-clinical or early-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials or studies. Likewise, the results of early clinical trials or pre-clinical studies of our product candidates may not be predictive of the results of planned

development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

The commencement and completion of pre-clinical studies and clinical trials may be delayed by several factors, including:

- failure to obtain regulatory authorization to commence a trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies;
- other regulatory issues, including the receipt of any inspectional observations on FDA's Form-483, Warning or Untitled Letters, clinical holds, or complete response letters or similar communications/objections by other regulatory authorities;
- unforeseen safety issues, or subjects experience severe or unexpected adverse events;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues, including those raised by the FDA or other regulatory authorities;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other regulatory authorities;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- an IRB or EC refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- premature discontinuation of study participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of our product candidate or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

In addition, disruptions caused by the COVID-19 pandemic increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Further, we, the FDA or other regulatory authorities may suspend our clinical trials in an entire country at any time, or an IRB/EC may suspend our clinical trial sites within any country, if it appears that we or our collaborators are failing to conduct a trial in accordance with applicable regulatory requirements, including Good Clinical Practice ("GCP") regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority finds deficiencies in our IND or equivalent applications for other countries or in the manner in which clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our

ability to generate product revenue from any of our product candidates, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a termination or suspension of, or delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional pre-clinical or clinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring product candidates to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing and authorization applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of any of our product candidates.

In addition, for our product candidates in clinical development, prior to our acquisition of the rights to those product candidates we had no involvement with or control over the pre-clinical or clinical development of those product candidates. We are therefore dependent on our licensing and other transaction partners having conducted such research and development in accordance with the applicable protocol and legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to product candidates, having correctly collected and interpreted the data from these trials and other research and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these product candidates. Problems associated with the pre-acquisition development of our product candidates could result in increased costs and delays in the development of our product candidates, which could harm our ability to generate any future revenue from sales of product candidates, if approved.

Our approach to the discovery and development of product candidates from our targeted protein degradation platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from this platform.

Treating diseases using targeted protein degradation is a new treatment approach. Our future success depends in part on the successful development of this novel therapeutic approach. Very few small molecule product candidates using targeted protein degradation have been tested in humans. None have been approved in the United States or Europe, and the data underlying the feasibility of developing these types of therapeutic products is both preliminary and limited. If any adverse learnings are made by other developers of chimeric targeting molecules, development of these product candidates could be materially impacted, which could in turn adversely impact our financial condition and future growth.

The scientific research that forms the basis of our efforts to develop our degrader product candidates is ongoing and the scientific evidence to support the feasibility of developing these treatments is both preliminary and limited. In addition, we may be unable to replicate the scientific evidence supporting our protein degrader candidates observed by our academic collaborators in commercial laboratories.

Further, certain cancer patients have shown inherent primary resistance to approved drugs that inhibit disease-causing proteins and other patients have developed acquired secondary resistance to these inhibitors. Although we believe our product candidates may have the ability to degrade the specific mutations that confer resistance to currently marketed inhibitors of disease-causing enzymes, any inherent primary or acquired secondary resistance to our product candidates in patients, or if the research proves to be contradicted, would prevent or diminish their clinical benefit.

We have not yet completed IND-enabling work for, or initiated a clinical trial of, any product candidate associated with our targeted protein degradation platform and we have not yet assessed the safety of any of these product candidates in humans. Although some of our product candidates have produced observable results in animal studies, there is a limited safety data set for their effects in animals. In addition, these product candidates may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result, there could be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

Additionally, the regulatory approval process for novel product candidates such as those associated with our targeted protein degradation platform is uncertain and can be more expensive and take longer than for other, better-known or extensively studied classes of product candidates. Although other companies are also developing therapeutics based on targeted protein degradation, no product candidates of this type have been approved in the United States or Europe. As a result, it is difficult for us to predict the time and cost of developing our product candidates and we cannot predict whether any of these product candidates will receive marketing approval or achieve commercial acceptance. Any development problems we experience in the future related to our targeted protein degradation platform or any of our related research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our pre-clinical studies or any clinical trials that we may initiate, as well as from commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Certain of our product candidates, including our gene therapy product candidates, are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

The manufacturing processes our contract manufacturing organizations (“CMOs”) use to produce our product candidates are complex, novel and have not necessarily been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers.

Our gene therapy product candidates may require processing steps that are more complex than those required for most small molecule drugs. Moreover, unlike small molecules, the physical and chemical properties of biologics generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or will perform in the intended manner. Accordingly, our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA, the EU or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other comparable regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other comparable regulatory authorities may require

that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

Our CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our manufacturing process could restrict our ability to meet potential future market demand for products.

We may encounter difficulties enrolling and retaining patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials for our product candidates on current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical trials for these product candidates. Enrollment in our clinical trials may also be slower than we anticipate, or be stopped, leading to delays in the development timelines for our product candidates.

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our product candidates, including batoclimab, which targets certain rare autoimmune indications, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. In addition, for certain of our early-stage development programs, there may be a limited number of sites where it is feasible to run clinical trials, making such programs particularly susceptible to delays caused by issues at those sites.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. For example, in February 2021, our subsidiary, Immunovant, voluntarily paused dosing in its clinical trials for batoclimab globally due to elevated total cholesterol and low-density lipoprotein ("LDL") levels observed in some patients treated with batoclimab, resulting in a delay in Immunovant's development of batoclimab. In future trials of batoclimab, it may be more difficult for Immunovant to recruit and retain patients for such clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper

and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

The results of our clinical trials may not support our proposed claims for our product candidates, or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior pre-clinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our clinical trials of batoclimab will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results in earlier pre-clinical studies or clinical trials. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. In February 2021, our subsidiary, Immunovant, voluntarily paused dosing in its clinical trials for batoclimab globally due to elevated total cholesterol and LDL levels observed in patients treated with batoclimab, resulting in a delay in Immunovant's development of batoclimab. Immunovant is progressing discussions with the FDA and is planning to progress discussions with other regulatory authorities, with the intent to continue development of batoclimab. While the ASCEND GO-2 trial was terminated and the efficacy results, based on approximately half the anticipated number of subjects who had reached the week 13 primary efficacy analysis at the time of the termination of the trial, were inconclusive, further discussions with external experts are ongoing to determine whether a specific population can be identified to optimize the clinical performance of batoclimab. Based on these analyses, Immunovant intends to re-initiate a placebo-controlled trial contingent upon achieving alignment with the ophthalmology division of the FDA. Failure to successfully complete clinical trials of batoclimab and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab would significantly harm our business.

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon our product candidates. Any delay in, or termination of, our clinical trials will delay the submission of an NDA or other similar applications to the FDA or other relevant comparable non-U.S. regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenues. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidates. The FDA has substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of product candidates under development result in the submission of an NDA or other similar application to the FDA and other comparable non-U.S. regulatory authorities and even fewer are approved for commercialization.

Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line

results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously published. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize product candidates, our business, operating results, prospects or financial condition may be harmed.

Changes in methods of product manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through pre-clinical studies to pivotal clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. Similar requirements apply in other jurisdictions. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenues.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. In addition, we rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future non-clinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and that clinical trial sites meet applicable protocol and regulatory requirements, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and other comparable non-U.S. regulatory authorities, which also require compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines for any of our product candidates that are in pre-clinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial

sponsors, principal investigators and clinical trial sites. Although we may rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our expected reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable non-U.S. regulatory authorities may reject our marketing applications and require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Failure by any future CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can adversely impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with the CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical supplies and commercial supplies of our product candidates and any future product candidate.

We do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We will rely on third parties to produce clinical and commercial supplies of our product candidates and any future product candidate.

Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our product candidates or any future product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our pre-clinical studies, clinical trials, research and development operations and commercialization. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably

delay completion of our clinical trials, product testing and potential regulatory approval of our product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates. Moreover, as a result of projected supply constraints for certain materials used in the production of our product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involves committing substantial financial resources to current or future potential product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals are pending to, among other things, prevent drug shortages and reduce the dependency of the United States on foreign supply chains and manufacturing. While we are still assessing these developments, they could impact our selection and utilization of CMOs, vendors and other suppliers and could have a material adverse impact on our business, financial condition and results of operations.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or other similar application to the FDA. Such facilities must also register with the FDA. Similar requirements apply in other jurisdictions. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with Current Good Manufacturing Practice ("cGMP") requirements for the manufacture of drug product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable non-U.S. regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable non-U.S. regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations and standards, including cGMP and similar standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;

- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacturer of another company's product candidates;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our product candidates under specified storage conditions and in a timely manner.

Any of these events could lead to clinical trial delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our product candidates as well as potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, total or partial suspension of production, or suspension or revocation of manufacturing/import authorizations and GMP certificates.

If the contract manufacturing facilities on which we rely do not continue to meet regulatory requirements or are unable to meet our requirements, including providing an adequate supply, our business will be harmed.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in the issuance of inspectional observations on FDA's Form-483, Warning or Untitled Letters, similar communications/objections by other authorities, public safety alerts identifying our company or products and sanctions being imposed on us, including clinical holds, import alerts, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We and/or our CMOs must supply all necessary documentation in support of an NDA or similar regulatory application on a timely basis, and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, inspect the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure

of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a supplemental NDA or similar regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Accordingly, switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

If malignancies arise in patients treated with our gene therapy product candidates, including ARU-1801, under development at Aruvant Sciences ("Aruvant") or if there are other safety events that require us to halt or delay clinical development of ARU-1801 or other gene therapies, the development of those therapies would be delayed and the commercial potential of those therapies would be materially and negatively impacted.

A potentially significant risk in any gene therapy product candidate using viral vectors is that the vector will insert in or near cancer-causing oncogenes leading to uncontrolled clonal proliferation of mature cancer cells in the patient, known as insertional oncogenesis, which can lead to certain forms of cancer. In early 2021, a company developing a gene therapy for the treatment of sickle cell disease announced that one of its patients has developed acute myelogenous leukemia following treatment. While Aruvant has not experienced any similar safety events to date, any such events arising in patients treated with ARU-1801 could result in delays to the clinical development timeline, the suspension of clinical development altogether or, following approval by the FDA and/or other relevant regulatory authorities, if received, the product being removed from the market or its market opportunity being significantly reduced. In addition, the sickle cell disease population has an elevated underlying risk of malignancy. As a result, if patients treated with ARU-1801 develop a malignancy, it may be difficult for us to determine the underlying cause of the malignancy and the link, if any, to ARU-1801, potentially causing further delays to our clinical development timeline. Any of the foregoing issues arising in relation to ARU-1801 or other gene therapy product candidates could lead to adverse publicity and have a material adverse effect on our business and the price of our Common Shares.

Risks Related to Regulatory Approval and Commercialization of Our Product Candidates

Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulator may delay, limit or deny approval. If we are unable to obtain regulatory approval in one or more jurisdictions for any product candidates, our business will be substantially harmed.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable non-U.S. regulatory authorities is lengthy and unpredictable, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of non-clinical or clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. To date, we have not obtained regulatory approval for any product candidates, and it is possible that our current product candidates and any other product candidates which we may seek to develop in the future will not ever obtain regulatory approval. We cannot be certain that any of our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Obtaining marketing approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process and the FDA or other non-U.S. regulatory authorities may delay, limit or deny approval of a product candidate for many reasons, including:

- we may not be able to demonstrate that a product candidate is safe and effective as a treatment for the targeted indications, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication, to the satisfaction of the FDA or other relevant regulatory authorities;
- the FDA or other relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase costs and prolong development timelines;
- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of clinical trials, including the design of proposed pre-clinical and early clinical trials of any future product candidates;
- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact the clinical trials and ability to obtain marketing approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical, pre-clinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, pre-clinical studies or clinical trials or may require additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites;
- if an NDA, BLA or a similar application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical, pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy ("REMS") or its equivalent, as a condition of approval;

- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or patient registries for product candidates;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidate;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Our future success depends significantly on our ability to successfully complete clinical trials for our product candidates, obtain regulatory approval and then successfully commercialize those product candidates. Any inability to successfully initiate, conduct or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional non-clinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from non-clinical and clinical research conducted using earlier versions of these product candidates. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize product candidates and may harm our business and results of operations.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down the product candidate development and approval process and delay or potentially jeopardize our ability to receive regulatory approvals, commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and have a negative impact on the price of our Common Shares.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive non-clinical studies, pre-clinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable non-U.S. regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product

candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable non-U.S. regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

Adverse events caused by our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidates or those from other companies targeting similar diseases, could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. For example, in February 2021, our subsidiary Immunovant voluntarily paused dosing in its ongoing trials for batoclimab globally due to elevated total cholesterol and LDL levels observed in patients treated with batoclimab, resulting in a delay in Immunovant's development of batoclimab. Any of these occurrences may harm our business, financial condition and prospects.

Furthermore, if any of our product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, vary, or limit their approval of the product or require a REMS (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require that we recall a product;
- additional restrictions being imposed on the marketing or manufacturing processes of product candidates or any components thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, require other labeling changes of a product or require field alerts or other communications to physicians, pharmacies or the public;
- we may be required to change the way a product is administered or to conduct additional clinical trials, change the labeling of a product or conduct additional post-marketing studies or surveillance;
- we may be required to repeat pre-clinical studies or clinical trials or terminate programs for a product candidate, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our products;
- our product candidates may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates and have a negative impact on the price of our Common Shares.

The regulatory approval processes of the FDA and comparable non-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable non-U.S. regulatory agencies, that such product candidate is safe and effective and, as applicable, pure and potent for its intended use. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions, cause a loss of patient confidence in us or our products, among other negative consequences.

Quality management plays an essential role in contract manufacturing of drugs or drug products, conducting clinical trials, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our product candidates. Our goal is to maintain a robust quality management program which includes the following broad pillars of quality:

- monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good applicable practice (“GxP”) (e.g., GCP, GLP and GMP regulated) products;
- monitoring and providing oversight of all GxP suppliers (e.g., contract development manufacturing organizations and CROs);
- establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and
- cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality.

Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, monetary sanctions, injunction to halt manufacture and distribution of drugs or drug products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal, suspension or variation of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, or a loss of patient confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of potential future sales, which could have an adverse effect on our business, financial condition, and results of operations.

Even if we obtain FDA approval for a product candidate in the United States, we may never obtain approval for or commercialize our product candidates in any other jurisdiction, which would limit our ability to realize the drug candidate's full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional pre-clinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be sold in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking regulatory approval outside of the United States could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The regulatory approval outside of the United States process may include all of the risks associated with obtaining FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Even if we obtain regulatory approval for our product candidates, we will still face extensive ongoing quality and regulatory obligations and continued regulatory review, which may result in significant additional expense, and our product may face future development and quality or regulatory compliance difficulties.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, traceability, conduct of potential post-market studies and post-market submission requirements, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with current cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, prior notification/review and/or approval of advertising and promotional materials by the competent authorities, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If a product candidate receives marketing approval, the accompanying label may limit the approved use of the drug or the FDA or other regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning, be included in the product labeling, which could limit sales of the product.

The FDA and other relevant regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulates the post-

approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and that promotional and advertising materials and communications are truthful and non-misleading. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications and if we do not market our product candidates for their approved indications or in a manner which regulators believe to be truthful and non-misleading, we may be subject to enforcement action. Moreover, in the EU we will be prohibited from promoting prescription-only medicinal products of individuals who are not healthcare professionals. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non-U.S. regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in other jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may negatively impact our business and the price of our Common Shares and may yield various results, including:

- restrictions on the manufacture such product candidates;
- restrictions on the labeling or marketing of such product candidates, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the United States);
- Warning or Untitled Letters or similar communications from other relevant regulatory authorities;
- withdrawal of the product candidates from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any current or future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance can also result in significant financial penalties.

Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation or orphan drug designation by the FDA or other relevant regulatory authorities, even if granted for any product candidate, may not lead to a faster development, regulatory review or approval process, and does not necessarily increase the likelihood that any product candidate will receive marketing approval in the United States or other jurisdictions.

We have sought, or may in the future seek, Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation or orphan drug designation for certain of our product

candidates. ARU-1801, a gene therapy in development by Aruvant for the treatment of sickle cell disease, has received orphan drug designation and rare pediatric disease designation by the FDA, as well as priority review and orphan designation by the EMA. In addition, two gene therapies under development by Sio Gene Therapies, AXO-AAV-GM1, in development for the treatment of GM1 gangliosidosis, and AXO-AAV-GM2, in development for the treatment of GM2 gangliosidosis, also known as Tay-Sachs and Sandhoff diseases, have received rare pediatric disease designation and orphan drug designation (in the case of AXO-AAV-GM1) and rare pediatric disease designation (in the case of AXO-AAV-GM2) from the FDA.

A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in potentially less efficacious control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a breakthrough therapy, the FDA may later decide that such product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not necessarily experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if we believe that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

Regulatory authorities in some jurisdictions, including the United States and the European Economic Area (the "EEA"), may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals annually in the United States or for which there is no reasonable expectation that costs of research and development of the drug for the disease or condition can be recovered by sales of the drug in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same orphan indication for that time period. In the United States, in order for a product to receive orphan drug exclusivity, FDA must not have previously approved a drug considered the same drug for the same orphan indication, or the subsequent drug must be shown to be clinically superior to such a previously approved same drug. The applicable period is seven years in the United States. A similar data exclusivity scheme exists in the EEA, the European Commission, on the basis of a scientific opinion by the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or

treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, orphan designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the "normal" data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company's pre-clinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic drug can be marketed for ten years from the first approval of the innovator drug in the EEA; the innovator drug may qualify for an extra year's protection. This additional one year of marketing exclusivity may be obtained where the innovator company is granted a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic company can only market their product after 11 years from the first grant of the innovator company's marketing authorization for the product in the EEA.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. In the EEA, orphan drug designation, and the related benefits, may be lost if it is established before the market authorization is granted that the designation criteria are no longer met.

Moreover, the ten year orphan market exclusivity in the EEA may be reduced to six years if the orphan drug designation criteria are no longer met at the end of the fifth year since grant of the approval, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

If we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug for a different condition or the same condition if the FDA or the EMA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EEA, a marketing authorization may also be granted, for the same therapeutic indication, to a competitor with a similar medicinal product during the exclusivity period if we are unable to supply sufficient quantities of the medicinal product for which we received marketing authorization. Upcoming legislative reforms in the EU may result in a reduction of market exclusivity periods for orphan medicinal products and/or imposition of additional requirements for grant of such exclusivity.

Certain of our gene therapy product candidates are based on novel technologies and the regulatory landscape that governs these product candidates we may develop is rigorous, complex, uncertain and subject to change, which makes it difficult to predict the time and cost of developing the product candidates and subsequently obtaining regulatory approval.

The clinical study requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product candidates. The regulatory approval process for novel product candidates such as our gene therapies can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Currently, a limited number of gene therapy products have been approved by the FDA, the EMA and the European Commission. Given the few precedents of approved gene therapy products, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the EU or other jurisdictions. Approvals by the EMA and the European Commission may not be indicative of what the FDA may require for approval.

Regulatory requirements governing the development of gene therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within the Center for Biologics Evaluation and Research (the "CBER"), to consolidate the review of gene therapy and related products, and to advise the CBER on its review. The FDA can put an IND on clinical hold if the information in an IND is not sufficient to assess the risks in pediatric patients. In addition to FDA oversight and oversight by IRBs, under guidelines promulgated by the National Institutes of Health ("NIH") gene therapy clinical trials funded by NIH are also subject to review and oversight by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB, and, where applicable, its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Adverse developments in pre-clinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as our gene therapies can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. In addition, because of the evolving regulatory landscape for novel product candidates such as our gene therapies, there is a heightened risk relating to changes in regulatory requirements, such as the required trial size, the size of safety databases and duration of clinical follow-up required for approval, which could develop in a manner that adversely impacts our business, financial condition and results of operations.

Further, as we are developing novel potential treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. The prospectively designed natural history studies with the same endpoints as our corresponding clinical trials may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

The commercial success of our product candidates will depend upon their degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance

for any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments, including any similar generic treatments;
- the ability to offer these products for sale at competitive prices;
- the ability to offer appropriate patient financial assistance programs, such as commercial insurance co-pay assistance;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA or comparable non-U.S. regulatory agencies;
- product labeling or product insert requirements of the FDA or other comparable non-U.S. regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is dispensed or distributed;
- the timing of market introduction of competitive products;
- publicity concerning these products or competing products and treatments;
- the strength of marketing and distribution support;
- favorable third-party coverage and sufficient reimbursement; and
- the prevalence and severity of any side effects or AEs.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe such products.

If approved, our product candidates regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway under section 351(k) of the Public Health Service Act ("PHSA") for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, a section 351(k) application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product submitted under section 351(a) of the PHSA containing the competing sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA and the FDA only approved the first interchangeable biosimilar in July 2021. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples legislation, purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, including by allowing generic drug, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biological product samples. While the full impact of these provisions is unclear at this time, its provisions do have the potential to facilitate the development and future approval of biosimilar versions of our products, introducing biosimilar competition that could have a material adverse impact on our business, financial condition and results of operations.

Whether approval of a biological product qualifies for reference product exclusivity turns on whether FDA consider the approval a "first licensure." Not every licensure of a biological product is considered a "first licensure" that gives rise to its own exclusivity period. We believe that our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

If, in the future, we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell, market and distribute any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have any infrastructure for the sales, marketing or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, compliance, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to market and sell our product candidates, if and when they are approved. We may also elect to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to selected product candidates, indications or geographic territories, including territories outside the United States, although there is no guarantee we will be able to enter into these arrangements even if the intent is to do so.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- the inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;

- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of any product candidate, we may be forced to delay potential commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring any product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to our product candidate or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop internally. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us or them. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, patient support, charitable organizations, customers, and others are subject to applicable healthcare regulatory laws, which could expose us to penalties and other risks.

Our business operations and current and potential future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, charitable organizations, customers, and others, expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates for which we obtain marketing approval. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program (such as Medicare and Medicaid). The term “remuneration” has been broadly interpreted by the federal government to include anything of value. Although there are a number of statutory exceptions and

regulatory safe harbors protecting certain activities from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal false claims laws, including the False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim; or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties currently ranging from $11,665 to $23,331 for each false claim or statement for penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most healthcare providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personal data and health information;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government

information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

- analogous state and EU and foreign national laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and several recently passed state laws that require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes, some of which contain ambiguous requirements that government officials have not yet clarified; and EU and foreign national laws prohibiting promotion of prescription-only medicinal products to individuals other than healthcare professionals, governing strictly all aspects of interactions with healthcare professionals and healthcare organizations and requiring public disclosure of transfers of value made to a broad range of stakeholders, including healthcare professionals, healthcare organizations, medical students, physicians associations, patient organizations and editors of specialized press.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other applicable health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena, civil investigative demand or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs for pharmaceuticals. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, with unpredictable and uncertain results. Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. Pursuant to the CARES Act and subsequent legislation, these reductions were suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. As the legislation currently stands, the reductions will go back into effect as of January 2022 and will remain in effect through 2030 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and reform government program reimbursement methodologies for drugs. Current Congressional proposals include direct price negotiation by Medicare in Medicare Parts B and D, international reference pricing for certain Medicare drugs, and inflationary rebates on Part B and Part D drugs whose prices increase above a certain amount, and Part D drug benefit redesign. At the federal level, the former Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services ("HHS") implemented several of these provisions to date. In May 2019, Centers for Medicare and Medicaid Services (the "CMS"), issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and

manufacturers. These modifications to the safe harbors are being challenged in court and HHS has delayed their implementation until January 1, 2023; however, the rule may be repealed through legislative action before such time. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Several pending legislative efforts, including President Biden's larger Build Back Better legislative agenda and draft bill text, incorporate these drug pricing reforms in addition to inflationary rebates on Part B and Part D drugs that would be payable on commercial and governmental program utilization, policies aimed at redesigning the Medicare Part D benefit and adopting drug price transparency measures.

Recent federal legislation and actions by state and local governments in the United States may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

Moreover, upcoming legislative and policy changes in the EU, some of which may materialize as early as 2022, are aimed at increasing accessibility and affordability of medicinal products, as well as at increased cooperation between the EU Member States. Such initiatives may further impact the price and reimbursement status of our products in the future.

There have been, and likely will continue to be, legislative and regulatory proposals at the national and state levels in jurisdictions around the world directed at containing or lowering the cost of healthcare, including prescription drugs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of any approved product candidates that we develop will depend in part on the extent to which coverage and adequate reimbursement for these product candidates and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. The target patient populations for our drugs are often relatively small, as a result of which the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial

infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our product candidates. There is no assurance that our product candidates, if approved, would achieve adequate coverage and reimbursement levels.

In the United States, no uniform policy of coverage and reimbursement for product candidates exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product candidates. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our product candidates, to the extent that patients who are prescribed our product candidates, if approved, are not separately reimbursed for the cost of the product.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, product candidates. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices for product candidates. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some other jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, following approval. There can be no assurance that our candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in other countries where our product candidates are sold will not harm our ability to sell our product candidates profitably, if they are approved for sale.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost

containment measures, legislative developments in the EU or the EU Member State may harm our ability to sell our product candidates profitably, if they are approved for sale. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national EU Member States law. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. The healthcare budgetary constraints in most countries have resulted in restrictions on the pricing and reimbursement of medicines. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. All of this could affect our ability to commercialize our product candidates, if approved.

Recent federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our product candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act ("MMA") contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent implementation of the rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC"), for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Other Risks Related to Our Business and Industry

We depend on the knowledge and skills of our senior leaders, and may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We have benefited substantially from the leadership, performance and vision of our senior leaders, in particular, our founder and Executive Chairman, Vivek Ramaswamy, our Chief Executive Officer, Matthew Gline, and other senior executives of ours and of the Vants. We rely greatly on the investment experience and

medical and scientific expertise of our senior leadership team to identify product candidates and guide future investments and opportunities, as well as the drug development expertise of our and the Vants' senior leadership to guide the pre-clinical and clinical development of our product candidates. Our success will depend on our ability to retain our current management team. In addition, while we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relation to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. Competition for senior leadership in the healthcare investment industry is intense, and we cannot guarantee that we will be able to retain key personnel of ours or of the Vants.

Our senior leaders and key employees may terminate their positions with us at any time. Due to the small number of employees at some of the Vants, the loss of key employee may have a larger impact on our business.
In particular, we rely on a limited number of employees in certain key jurisdictions, including the United Kingdom (the "U.K."), Switzerland and Bermuda. If we lose one or more members of our or the Vants' senior leadership teams or other key employees, our ability to successfully implement our business strategies could be adversely impacted. Replacing these individuals may be difficult, cause disruption and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain "key person" insurance for any members of our senior leadership team or other employees.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided certain equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our share price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain invaluable employees, members of our management, scientific and development teams may terminate their employment with us at any time. Although we have employment agreements with our key employees, certain of these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time. Our success also depends on our ability to continue to attract, retain and motivate high skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Changes in funding for, or disruptions to the operations of, the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources in light of governmental "stay at home" orders in response to the COVID-19 pandemic, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC,

have had to furlough critical FDA, SEC and other government employees and stop critical activities. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold due to impacts of the COVID-19 pandemic, with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. In April 2021, the FDA issued guidance describing how it will request and conduct voluntary remote interactive evaluations of manufacturing and outsourcing facilities as well as facilities involved in non-clinical and clinical research. With respect to pre-approval inspections, the FDA has been using other tools and approaches where possible, including requesting existing inspection reports from other foreign regulatory partners, requesting information from applicants, and requesting records and other information directly from facilities and other inspected entities. Should the FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel and there are other identified deficiencies, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility without other identified deficiencies, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. If a prolonged government shutdown or disruption to the operations of the FDA occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown or disruption to the operations of the USPTO could prevent the timely review of our patent applications, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Future government shutdowns and similar events could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt operations.

In connection with our continued growth and the Business Combination, we expect to hire, either directly or through our current or future affiliates, additional employees for our managerial, finance and accounting, clinical, scientific and engineering, regulatory, operational, manufacturing, sales and marketing teams. We may have difficulties in connection with identifying, hiring, integrating and retaining new personnel. Future growth would impose significant additional responsibilities on management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of operations across our entities, which may result in weaknesses in infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and ability to commercialize product candidates and new technologies and compete effectively will partly depend on our ability to effectively manage any future growth.

Many of the other pharmaceutical and healthcare technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer

operating history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and our business will be harmed.

Our international operations may expose us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally.

Part of our business strategy involves potential expansion internationally with third-party collaborators to seek regulatory approval for our product candidates globally. Doing business internationally involves a number of risks, including but not limited to:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidate, if approved, in various countries;
- difficulties in managing operations in different jurisdictions;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to currency exchange rate fluctuations;
- varying protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the United States Foreign Corrupt Practices Act (the “FCPA”), including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010 (the “U.K. Bribery Act”), and similar anti-bribery and anti-corruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors’ activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our financial condition, results of operations and cash flows.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such

as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development and commercialization of products for the treatment of the indications that we are pursuing, including, but not limited to:

- Roflumilast, a PDE4 inhibitor, a potential competitor to tapinarof, in development by Dermavant Sciences (“Dermavant”) for the topical treatment of psoriasis and atopic dermatitis;
- Ruxolitinib, a topical Janus kinase inhibitor, a potential competitor to tapinarof, in development by Dermavant for the topical treatment of atopic dermatitis;
- Teprotumumab, an insulin-like growth factor-1 receptor inhibitor, a potential competitor to batoclimab, in development by Immunovant for the treatment of thyroid eye disease;
- Efgartigimod, an anti-FcRn antibody fragment, and nipocalimab, an anti-FcRn antibody, both potential competitors to batoclimab, in development by Immunovant for the treatment of myasthenia gravis; and
- CTX001, a gene-editing therapy, and LentiGlobin, a gene therapy delivering a modified form of adult hemoglobin, both potential competitors to ARU-1801, in development by Aruvant for the treatment of sickle cell disease.

If any of these or other competitors, including competitors for our other product candidates, receive FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as

in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The markets in which our healthcare technology Vants participate are competitive, and if we do not compete effectively, our business and operating results could be adversely affected.

The overall market for healthcare technologies and software is global, rapidly evolving, competitive and subject to changing technology and shifting customer focus. Our healthcare technology Vants, including Datavant, a healthcare data infrastructure company (in which we own a minority equity interest), Lokavant, a clinical trial technology company, and Alyvant, a salesforce technology company, face competition from well-established providers of these solutions, certain of which may have long-standing relationships with many of our current and potential customers, including large biopharmaceutical companies. We also face competition from solutions that biopharmaceutical companies develop internally and from smaller companies that offer products and services directed at more specific markets than we target, enabling these smaller competitors to focus a greater proportion of their efforts and resources on these markets, as well as a large number of companies that have been founded with the goal of applying machine learning technologies to drug discovery.

Many of our competitors are able to devote greater resources to the development, promotion, and sale of their software solutions and services. Third parties with greater available resources and the ability to initiate or withstand substantial price competition could acquire our current or potential competitors. Our competitors may also establish cooperative relationships among themselves or with third parties that may further enhance their product offerings or resources. If our competitors' products, services or technologies become more accepted than our solutions, if our competitors are successful in bringing their products or services to market earlier than ours, if our competitors are able to respond more quickly and effectively to new or changing opportunities, technologies, or customer requirements, or if their products or services are more technologically capable than ours, then the business and prospects of these Vants could be adversely affected.

We and our subsidiaries are subject to litigation and investigation risks which could adversely affect their business, results of operations and financial condition and could cause the market value of our Common Shares to decline. Insurance coverage may not be available for, or adequate to cover, all potential exposure for litigation and other business risks.

We and our subsidiaries are from time to time subject to various litigation matters and claims, including regulatory proceedings, administrative proceedings, securities litigation and other lawsuits, and governmental investigations. In addition, we and our subsidiaries may receive requests for information from governmental agencies in connection with their regulatory or investigatory authority or from private third parties pursuant to subpoena. These proceedings may be complex and prolonged, and may occupy the resources of us and our

subsidiaries' management and employees. These proceedings are also costly to prosecute and defend and may involve substantial awards or damages payable by us or our subsidiaries if not favorably resolved. We and our subsidiaries may be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings. We also face risks relating to litigation arising from judgments made by us and the Vants as to the materiality of any developments in our businesses, including with respect to pre-clinical and clinical data, and the resulting disclosure (or lack thereof) may give rise to securities litigation.

We maintain insurance policies for litigation and various business risks, but such policies may not be adequate to compensate us for potential losses. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention. Because of the uncertain nature of litigation, investigations and insurance coverage decisions, it is not possible to predict the outcome of these matters, which could have a material adverse effect on the business, results of operations, and financial condition of us and our subsidiaries, as applicable, could impact the ability to consummate a transaction that is challenged or otherwise subject to such litigation and could cause the market value of our Common Shares to decline.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our gene therapy product candidates and any future products or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our product candidates.

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in our clinical studies, potential regulatory delays in the testing or approval of our potential products, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any approved products.

We may not hold a controlling stake in certain of our subsidiaries and thus may not be able to direct our business or the development of our product candidates.

For certain of the Vants, including Arbutus, Datavant and Sio Gene Therapies, we hold less than a majority ownership interest or are otherwise limited in our ability to direct or control the business and the development of the product candidates or technologies at the Vant. In addition, for certain other Vants, including Immunovant, we may in the future come to hold less than a majority ownership interest in the Vant. Furthermore, even if we own a majority ownership interest in a Vant, we may not necessarily be able to control the outcome of certain corporate actions. If the business or development of a product candidate at one of these Vants were to face challenges, we would be adversely affected as a result and would be limited in our ability to cause or influence the Vant in question to take appropriate remediative actions.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Our computer systems, as well as those of various third parties on which we presently rely, or may rely on in the future, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, and/or other third parties. Any of the foregoing may compromise our system infrastructure, or that of our third-party

vendors and other contractors and consultants, or lead to data leakage. The risks of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, sovereign governments and cyber terrorists, have generally increased over time, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world.

We generally require our third-party providers to implement effective security measures and to identify and correct for any such failures, deficiencies or breaches. Although we seek to supervise such third parties' security measures, our ability to do so is limited. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We cannot anticipate all possible types of security threats and we cannot guarantee that our data protection efforts and our investments in information technology will prevent significant breakdowns, data leakages, security breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If any of the aforementioned security events were to occur, it could result in a material disruption of our drug development programs and business operations. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we rely on third parties to supply components for and to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and reputational damage and the further development of any product candidate could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business, including in particular our healthcare technology businesses.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues. Failure to comply with these laws and regulations could result in enforcement actions against us, including possible fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. At the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards for "covered entities" (group health plans and most healthcare providers) that limit the use and disclosure of individually identifiable health information those entities receive or create ("protected health information"), and require the implementation of administrative, physical and technological safeguards to protect the security, confidentiality, integrity and availability of electronic protected health information. While we generally are not subject to HIPAA in our business, we do business with various entities that are subject to HIPAA and we have to expend resources to understand their obligations, adjust contractual relationships in light of those obligations, or change business practices. Congress has considered expanding the scope of the HIPAA privacy and security regulations and we may in the future become subject to them ourselves, which would require additional expenditures and create additional risks.

In addition, many states in which we operate have laws that protect the privacy and security of personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act (the "CMIA"), a statute similar to HIPAA that expressly applies to pharmaceutical companies and companies that provide technologies for processing personal health information, imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information, with limited exceptions, and requires security measures to protect the information. The CMIA authorizes administrative fines and civil penalties of up to $25,000 for willful violations and up to $250,000 if the violation is for purposes of financial gain, as well as criminal fines. In addition, the California Consumer Privacy Act of 2018 (the "CCPA"), which went into effect on January 1, 2020, requires covered businesses to provide substantial disclosures to California residents and honor such residents' data protection and privacy rights, including the right to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the compromise of highly sensitive personal information, which may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended several times, including by the California Privacy Rights Act (the "CPRA"), a ballot initiative that passed in November 2020 which, among other things, created a new state agency vested with authority to implement and enforce the CCPA and the CPRA. Effective in most material aspects starting on January 1, 2023, the CPRA will expand California residents' rights with respect to certain sensitive personal information and give California residents' a right to opt out of the sharing of certain personal information for targeted online advertising. Virginia and Colorado also recently enacted CCPA/CPRA-like laws, the Virginia Consumer Data Privacy Act (the "VDCPA") and the Colorado Privacy Act ("CPA"), to provide their respective residents with similar rights. New legislation enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. The effects on our business of the CMIA, CCPA, CPRA, VDCPA, CPA and other similar state laws and general consumer protection authorities are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Outside of the United States, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in EEA, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on controllers, including *inter alia*: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with data protection rights of data subjects; and (iv) reporting of certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible). The GDPR also prohibits the transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. Until recently, one such data transfer mechanism was the EU-US Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union ("CJEU"). The CJEU upheld the validity of standard contractual clauses ("SCCs") as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA and the U.K., need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. It remains to be seen whether SCCs will remain available and whether additional means for lawful data

transfers will become available. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by customers and data subjects. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA. In June 2021, the CJEU issued a ruling that expanded the scope of the "one stop shop" under the GDPR. According to the ruling, the competent authorities of EU Member States may, under certain strict conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross- border processing activities, even such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority.

Further, as of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and EU (*i.e.*, following the United Kingdom's exit from the EU – otherwise known as Brexit), data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the United Kingdom's data protection framework, enabling data transfers from EU member states to the United Kingdom to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data.

If we or our third party service providers are unable to properly protect the privacy and security of personal information, or other sensitive data we process in our business, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties. Enforcement activity from state Attorneys General and agencies such as the California Privacy Protection Agency, the Federal Trade Commission, EU Data Protection Authorities and other regulatory authorities in relation to privacy and cybersecurity matters can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In the United States, the threat of class action lawsuits based on data security breaches or alleged unfair practices adds a further layer of risk. We cannot be sure how these privacy laws and regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. Significant resources are needed to understand and comply with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices or unwind certain lines of business, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors or potential collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our results of operations.

We are exposed to the risk that our or our affiliates' employees and contractors, including principal investigators, CROs, CMOs, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing and the FDA's GCP, GLP and GMP standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations.

Additionally, we are subject to the risk that a person, including any person who may have engaged in any fraud or misconduct, or government agency could allege such fraud or other misconduct, even if none occurred. Furthermore, we rely on our CROs and clinical trial sites to adequately report data from our ongoing clinical trials. Moreover, in some instances, our licensing partners conduct clinical trials with respect to product candidates in different territories and we rely on any such partners to share data from their ongoing clinical trials as required under our agreements with such partners. For example, any failure by such parties to adequately report safety signals to us in a timely manner from any such trials may also affect the approvability of our product candidates or cause delays and disruptions for the approval of our product candidates, if at all. If our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors are alleged or found to be in violation of any such regulatory standards or requirements, or become subject to a corporate integrity agreement or similar agreement and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and additional reporting requirements and oversight, any of which could harm our ability to operate our business and our results of operations.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any product candidates that we may develop.

The use of existing product candidates in clinical trials and the sale of any product candidates for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our product candidates. On occasion, large judgments have been awarded in class action lawsuits where drugs have had unanticipated harmful effects. If we cannot successfully defend

against product liability claims, it could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- delay or termination of clinical trials, or withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize existing product candidates or any future product candidate, if approved;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for existing product candidates or any future product candidate, if approved; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to acquire insurance coverage to include the sale of commercial product candidates; however, it may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates, if approved, that we develop.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Certain of our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We or the third parties upon whom we depend may be adversely affected by earthquakes, outbreak of disease or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our offices, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, product candidates, investigational medicines and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, our employees, affiliates and/or business partners may use social media for their personal use, and their activities on social media or in other forums could result in adverse publicity for us. Any negative publicity as a result of social media posts, whether or not such claims are accurate, could adversely impact us. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business. The use of social media also creates additional risks in the EEA and the UK where promotion of prescription-only medicines to patients and the general public is strictly prohibited. Social media content that is generated, shared or liked by our company or our directors, employees, staff or other representatives may potentially be perceived or construed as constituting prohibited promotion of prescription-only medicinal products and trigger enforcement and penalties. This is an area of increased scrutiny in both the EEA and the UK.

The United Kingdom's withdrawal from the European Union may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Our headquarters are located in the United Kingdom. The United Kingdom formally exited the EU, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the United Kingdom entered a transition period (the "Transition Period"), during which it continued to follow all EU rules. The Transition Period ended on December 31, 2020. On December 30, 2020, the United Kingdom and European Union signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties.

There is considerable uncertainty resulting from a lack of precedent and the complexity of the United Kingdom and the EU's intertwined legal regimes as to how Brexit (following the Transition Period) will impact the life sciences industry in Europe, including our company, including with respect to ongoing or future clinical

trials. The impact will largely depend on the model and means by which the United Kingdom's relationship with the EU is governed post-Brexit and the extent to which the United Kingdom chooses to diverge from the EU regulatory framework. For example, following the Transition Period, Great Britain will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorizations and our products will therefore require a separate marketing authorization to allow us to market such products in Great Britain. It is unclear as to whether the relevant authorities in the EU and the United Kingdom are adequately prepared for the additional administrative burden caused by Brexit. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from or delay us commercializing our product candidates in the United Kingdom and/or the EEA and restrict our ability to generate revenue and achieve and sustain profitability. In the short term, following the expiry of the Transition Period there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain. Further, under current plans, orphan designation in the United Kingdom (or Great Britain, depending on whether there is a prior centralized marketing authorization in the EEA) following Brexit is to be based on the prevalence of the condition in Great Britain as opposed to the current position where prevalence in the EU is the determinant. It is therefore possible that conditions that are currently designated as orphan conditions in the United Kingdom will no longer be and that conditions are not currently designated as orphan conditions in the European Union will be designated as such in the United Kingdom.

If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EEA for our product candidates, which could significantly and materially harm our business. There is a degree of uncertainty regarding the overall impact that Brexit will have on (i) the marketing of pharmaceutical products, (ii) the process to obtain regulatory approval in the United Kingdom for product candidates or (iii) the award of exclusivities that are normally part of the EU legal framework (for instance Supplementary Protection Certificates, Pediatric Extensions or Orphan exclusivity).

Brexit may also result in a reduction of funding to the EMA once the United Kingdom no longer makes financial contributions to European institutions, such as the EMA. If funding to the EMA is so reduced, it could create delays in the EMA issuing regulatory approvals for our product candidates and, accordingly, have a material adverse effect on our business, financial condition, results of operations or prospects.

In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business.

As a result of Brexit, other EU Member States may seek to conduct referenda with respect to their continuing membership with the EU. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the EU will have and how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect

the intellectual property related to our brand, current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and any future product candidates. We seek to protect our proprietary position by in-licensing or acquiring intellectual property and filing patent applications in the United States and abroad related to our current and future development programs and product candidates, defending our intellectual property rights against third-party challenges and enforcing our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, there is always a risk that our licensed or owned issued patents and any pending and future patent applications may not protect our product candidates, in whole or in part, and may not effectively prevent others from commercializing competitive product candidates, or that an alteration to our product candidates or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of their research and development output, such as employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, while we have pre-publication review procedures in effect, premature or inadvertent publication of potentially patentable subject matter could preclude our ability to obtain patent protection. We may choose not to seek patent protection for certain innovations or product candidates and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, product candidates may not be protected by patents in all jurisdictions. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell product candidates and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell product candidates and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. The patent applications that we own or in-license may fail to result in issued patents with claims that cover product candidates in the United States or in other countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable in enforcement and other adversarial proceedings.

The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or any future product candidate in the United States or in other countries. Our pending patent applications at the Patent Cooperation Treaty (the “PCT”) are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. For example, any issued patents might not cover the pharmaceutical composition of the product candidate that is ultimately commercialized. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may ultimately obtain. Even if patents do successfully issue and even if such patents cover our product candidates or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result

in such patents being narrowly construed, invalidated, or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar product candidates or limit the length of terms of patent protection we may have for our product candidates and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing product candidates or practicing our own patented technology or impose a substantial royalty burden to do so. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidates or other technologies, competitors and other third parties could market product candidates and use processes that are substantially similar to, or superior to, ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a materially adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The standards that the U.S. Patent and Trademark Office (the "USPTO") and its counterparts in other countries use to grant patents are not always applied predictably or uniformly. In addition, the laws of countries other than the United States may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in such jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Other parties have developed technologies that may be related or competitive to our own technologies and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own or licensed patent applications or issued patents. Furthermore, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act ("the Leahy-Smith Act"), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act was signed into law on September 16, 2011 and includes a number of significant changes to U.S. patent law. These include provisions

that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We are currently and may in the future be subject to third-party pre-issuance submissions of prior art to the USPTO or its equivalents and we or our licensors have in the past, and may in the future, become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the U.S. or in other jurisdictions challenging our patent rights or the patent rights of others. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. For example, three U.S. patents (U.S. Patent Nos. 8,058,069, 9,364,435 and 9,404,127) relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH, as assignee of Genevant Sciences Ltd. ("Genevant"), exclusively licenses from Arbutus Biopharma Corp. ("Arbutus") were the subject of *inter partes* review proceedings brought by Moderna Therapeutics, Inc. ("Moderna") before the Patent Trial and Appeal Board of the USPTO ("PTAB"). The PTAB upheld all claims of U.S. Patent No. 8,058,069, invalidated some of the claims of U.S. Patent No. 9,364,435 and invalidated all claims of U.S. Patent No. 9,404,127. The United States Court of Appeals for the Federal Circuit (the "Federal Circuit") heard oral arguments with respect to U.S. Patent Nos. 8,058,069 and 9,364,435 in October 2021. On December 1, 2021, the Federal Circuit issued decisions in both proceedings. The Federal Circuit affirmed the PTAB's decision that upheld all claims of U.S. Patent 8,058,069. The Federal Circuit affirmed the PTAB's decision invalidating certain claims of U.S. Patent 9,364,435 but dismissed Moderna's appeal with respect to those claims that the PTAB upheld for lack of standing. The Federal Circuit vacated and remanded the PTAB's decision on U.S. Patent No. 9,494,127. The PTAB's decision with respect to U.S. Patent No. 9,494,127 had been held in administrative abeyance pending a review following a recent Supreme Court ruling in an unrelated case. The matter is now pending before the Federal Circuit and at the briefing stage. Additionally, one European patent (EU patent no. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licenses from Arbutus is the subject of an opposition proceeding brought by Merck Sharp & Dohme Corporation and Moderna at the European Patent Office Opposition Division. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights or result in our breach of agreements pursuant to which we license such rights to our collaborators or licensees. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent

claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that falls outside the scope of our patent protection. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, are limited. Without patent protection for our current or future product candidates, it may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our own and, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms and their scope may be inadequate to protect our competitive position on current and future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, are limited. Even if patents covering product candidates are obtained, once the patent life has expired, we may be open to competition from competitive product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, the patent covering the use of tapinarof as an active ingredient to treat psoriasis and atopic dermatitis, but not limited to any formulation, expired in December 2020. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

We do not currently and may not in the future own or license any issued composition of matter patents covering certain of our product candidates, including tapinarof, and we cannot be certain that any of our other issued patents will provide adequate protection for such product candidates.

Composition-of-matter patents on the active pharmaceutical ingredient (“API”) in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. While we generally seek composition of matter patents for our product candidates, such patents may not be available for all of our product candidates. For example, we do not own or in-license any issued composition of matter patents in the United States or any other jurisdiction with respect to tapinarof. Instead, we rely on an issued U.S. patent claiming topical formulations of tapinarof, including the formulation studied in Phase 3, and an issued U.S. patent covering methods of using the patented topical formulations to treat inflammatory diseases, including psoriasis and atopic dermatitis. The formulation and method-of-use patents have natural expiration dates in 2036. We additionally rely on a drug substance (“DS”) patent covering the high purity commercial crystal form of the DS, the commercial DS synthesis and several novel intermediates that are formed in the synthesis, which has a natural expiration date in 2038.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect

to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

Our owned and licensed patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own or license with respect to our product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidate begins to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of product candidates, one or more of our U.S. patents may be eligible for a limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data to obtain approval of competing product candidates following our patent expiration and launch their product earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated as a result of non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of the patent. The USPTO and various national or

international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent applications, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or any future product candidate, our competitors might be able to enter the market earlier than anticipated, which would have an adverse effect on our business.

We rely on certain in-licensed patents and other intellectual property rights in connection with our development of certain product candidates and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our ability to develop and commercialize product candidates is dependent on licenses to patent rights and other intellectual property granted to it by third parties. Further, development and commercialization of our current product candidates, and development of any future product candidates, may require us to enter into additional license or collaboration agreements.

Our current license agreements impose, and future agreements may impose, various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we may not be able to market our product candidates. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms. Additionally, certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. For example, disputes may arise with respect to our current or future licensing agreement include disputes relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our technology and product candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreements and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and

commercialize our product candidates. If our licenses are terminated, we may lose our rights to develop and market our technology and product candidates, lose patent protection for our product candidates and technology, experience significant delays in the development and commercialization of our product candidates, or incur liability for damages. In addition, we may need to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our product candidates.

Furthermore, if our licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. In addition, certain of these license agreements, may not be assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that it licenses from third parties. For example, pursuant to the license agreement we have with the Cincinnati Children's Hospital Medical Center ("CCHMC"), CCHMC controls such activities for certain patents licensed to ASG under such agreement, subject to ASG's right to review and comment. Therefore, we cannot be certain that these or other patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. Additionally, we may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. If our current or future licensors or collaboration partners fail to obtain, maintain, defend, protect or enforce any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize product candidates that are the subject of such licensed rights could be adversely affected.

Furthermore, certain of our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. The intellectual property portfolio licensed to us by our licensors at least in some respects, may therefore be used by such licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. For example, Immunovant does not have rights to develop, manufacture, use or commercialize batoclimab or file or enforce patents relating to these assets in territories other than the United States, Canada, Mexico, the EU, the U.K., Switzerland, the Middle East, North Africa and Latin America, as such rights in other jurisdictions have been retained by HanAll Biopharma Co., Ltd. ("HanAll") or licensed by HanAll to third parties. Additionally, Dermavant does not have the right to develop, manufacture, use or commercialize tapinarof in China, including Hong Kong, Macau or Taiwan, as such rights were retained by Welichem Biotech Inc. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

Third party claims or litigation alleging infringement, misappropriation or other violations of third-party patents or other proprietary rights or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of our product candidates and any future product candidate.

Our commercial success depends in part on our avoidance of infringement, misappropriation and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review, and post-grant review before the USPTO, as well as oppositions and similar processes in other jurisdictions. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, we are aware of third-party patents and patent applications that, if issued as patents, could be construed in a manner that negatively impacts the commercialization of ARU-1801. If any such patents were held by a court of competent jurisdiction to cover ARU-1801, we may be required to cease development or commercialization of ARU-1801 unless we obtain a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms, may only be available on a non-exclusive basis or may not be available at all. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents.

Additionally, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could be time-consuming and divert the attention of senior management.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual

property claim against it, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because the competitors have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our product candidates, services, and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our Common Shares.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might harm our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates, any future product candidates, or the use thereof, provided such pending patent applications result in issued patents. Our ability to develop and market our product candidate or any future product candidates can be adversely affected in jurisdictions where such patents are issued.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect and we may incorrectly conclude that a third-party patent is invalid or unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates or any future product candidates, if approved.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time-consuming, even if ultimately successful. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives, or could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or non-statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. Additionally, any adverse outcome could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our Common Shares.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Because many of the patents we own are owned by our subsidiaries, and in certain cases by subsidiaries that are not or will not be directly commercializing products, we may not be in a position to obtain a permanent injunction against a third party that is found to infringe our patents.

Many patents that we own are assigned to our subsidiaries or to their respective subsidiaries. For example, any patents that Immunovant owns are assigned to its wholly-owned subsidiary Immunovant Sciences GmbH and any patents that Dermavant owns are assigned to its wholly-owned subsidiary Dermavant Sciences GmbH. If a third party is found to be infringing such patents, we and our direct subsidiaries may not be able to permanently enjoin the third party from making, using, offering for sale or selling the infringing product or activity for the remaining life of such patent in the United States or other jurisdictions when the patent is assigned to a subsidiary, which is not the entity that is or would be commercializing a potentially competitive product or service. In such a circumstance, such third party may be able to compete with us or our subsidiaries, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or USPTO rules and regulations could increase the uncertainties and costs.

The United States has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. For example, the Biden administration recently indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID-19 vaccines. Any waiver of our patent or other intellectual property protection by the U.S. and other foreign governments, including with respect to Genevant’s licensed lipid nanoparticle (“LNP”) delivery technology as used in connection with Messenger RNA vaccine delivery, could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and non-U.S. legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." For example, the research resulting in certain of our in-licensed patent rights and technology for certain product candidates was funded in part by the U.S. federal government. As a result, the federal government may have certain rights to such patent rights and technology, which include march-in rights. If the federal government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The federal government's rights may also permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The federal government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. Further, the recipient of U.S. government funding is required to comply with certain other requirements, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. The U.S. government has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times, or be able to rectify any lapse in compliance with these requirements. Any exercise by the government of any of the foregoing rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates or patents that cover our biologic product candidates can be challenged by third parties.

If one of our product candidates is approved by the FDA and if a third party files an application under Section 505(b)(2) or an abbreviated new drug application ("ANDA") under Section 505(j) for a generic product containing any of our product candidates, including tapinarof (which, following the natural expiration of our method of use patent family, will be protected only by our formulation patent), and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic product. A certification under 21 CFR § 314.94(a)(12)(i)(A)(4) that the new product will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If

the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products before an ANDA or 505(b)(2) NDA is filed we will be unable to obtain a 30-month stay of FDA approval of a 505(b)(2) or ANDA.

For example, our three issued U.S. patents covering tapinarof may not provide adequate protection from competitive products developed by 505(b)(1) NDA, 505(b)(2) NDA or 505(j) ANDA applicants containing paragraph IV certifications if such applicants are able to design around the three patents. One or more competitors may circumvent these patents by filing a marketing application with the FDA under Sections 505(b)(2) or 505(j) of the Federal Food, Drug and Cosmetic Act containing a paragraph IV certification for a competitive product containing the active moiety in tapinarof and successfully challenging the validity of the three patents or successfully designing around the three patents. Any successful challenge against the three patents and/or designing around one or more of the patents could result in a generic version of tapinarof being commercialized before the expiration of the three patents. If the three patents are successfully challenged or designed around, our business, results of operations, financial condition and prospects would be harmed.

For biologics, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological product candidates. Due to the large size and complexity of biological product candidates, as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA does not require reference product sponsors to list patents in the FDA's Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims, it could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or result in a finding of non-infringement.

If we are unsuccessful in enforcing our patents against generics or biosimilars, our products could face competition prior to the expiration of the patents which cover such products, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, any such litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws of the United States.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing product candidates made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and may also export infringing product candidates to territories where we have patent protection, but enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in all countries in which a market may exist. Moreover, in jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in other countries product candidates and services that are the same as or similar to our product candidates and services, and our competitive position would be harmed.

Many companies have encountered significant problems in protecting and defending intellectual property rights in other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology product candidates, which could make it difficult for us to stop the infringement of our patents or marketing of competing product candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of any trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for any product candidates, we may rely on trade secrets, including unpatented software, know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect this software and information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants.

Because we rely and expect to continue to rely on third parties to manufacture our product candidates and future product candidates, and we collaborate and expect to continue to collaborate with third parties on the development of current and future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of

our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in the market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors and other third parties may discover our trade secrets, including our proprietary software, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's or other third party's discovery of our trade secrets, including our proprietary software, would impair our competitive position and have an adverse impact on our business.

We cannot guarantee that we have entered into non-disclosure, confidentiality agreements, material transfer agreements or consulting agreements with each party that may have or have had access to our trade secrets or proprietary software, technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and proprietary software, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets, including our proprietary software, were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, including our proprietary software, were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

Certain software utilized in our computational drug discovery efforts may include third party open source software. Any failure to comply with the terms of one or more open source software licenses could adversely affect our business, subject us to litigation, or create potential liability.

Certain software utilized in our computational drug discovery efforts may include third party open source software and we expect to continue to incorporate open source software in the future. The use of open source software involves a number of risks, many of which cannot be eliminated and could negatively affect our

business. For example, we cannot ensure that we have effectively monitored our use of open source software or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming infringement on such third parties' intellectual property rights. Litigation could be costly for us to defend, have a negative effect on our business, financial condition and results of operations, or require us to devote additional research and development resources to modify our computational drug discovery platform.

Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties, controls on the origin of the software or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our solutions. By the terms of certain open source licenses, if portions of our proprietary software are determined to be subject to an open source license or if we combine our proprietary software with open source software in a certain manner, we could be required to release the source code of our proprietary software and to make our proprietary software available under open source licenses, each of which could reduce or eliminate the effectiveness of our computational discovery efforts. We may also face claims alleging noncompliance with open source license terms or misappropriation or other violation of open source technology. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at universities or other software, biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to not use the confidential information of their former employer, we may be subject to claims that we or our employees, consultants, independent contractors or other third parties have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our owned or licensed patents or patent applications. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, could limit the duration of the patent protection covering our technology and product candidates and could result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our current or future product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may harm our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would harm our business, results of operations and financial condition.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We rely on a combination of internally developed and in-licensed intellectual property rights and we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or other third parties who are involved in developing product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, contractors and other third parties who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our invention assignment agreements may not be self-executing or may be breached, and we may not have adequate remedies for any such breach. Additionally, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities, and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could adversely impact the price of our Common Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs, or in-license needed technology or other future product candidates. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize product candidates, if approved. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary intellectual property rights to future product candidates through acquisitions and in-licenses.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. Accordingly, we may seek to acquire or in-license patented or

proprietary technologies to develop such product candidates or to grow our product offerings and technology portfolio. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidate or technology from third parties on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on non-exclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. In that event, we may be unable to develop or commercialize such product candidates or technology. We may also be unable to identify product candidates or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such product candidate and technology.

The in-licensing and acquisition of third-party intellectual property rights for any future product candidate is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for any future product candidate and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates or technology on terms that would allow us to make an appropriate return on our investment.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish product candidates that are approved for marketing from the product candidates of our competitors. Our current and future trademark applications in the United States and in other jurisdictions may not be allowed or may subsequently be opposed, challenged, infringed, circumvented, declared generic or determined to be infringing other marks. Additionally, once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties have in the past opposed, are currently opposing and may in the future oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage.

Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to product candidates, but that are not covered by the claims of the patents that we own;
- others may be able to make product candidates that are similar to product candidates that we intend to commercialize that are not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensor or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all;
- the patents of others may harm our business; and

- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, they could significantly harm our business and results of operations.

Risks Related to our Securities, our Jurisdiction of Incorporation and Certain Tax Matters

The listing of our securities on Nasdaq did not benefit from the process undertaken in connection with an underwritten initial public offering.

Our Common Shares and our Warrants are listed on Nasdaq under the symbols "ROIV" and "ROIVW," respectively. Unlike an underwritten initial public offering of our securities, the initial listing of our securities as a result of the Business Combination did not benefit from the following:

- the book-building process undertaken by underwriters that helps to inform efficient price discovery with respect to opening trades of newly listed securities;
- underwriter support to help stabilize, maintain or affect the public price of the new issue immediately after listing; and
- underwriter due diligence review of the offering and potential liability for material misstatements or omissions of fact in a prospectus used in connection with the securities being offered or for statements made by its securities analysts or other personnel.

The lack of such a process in connection with the listing of our securities could result in diminished investor demand, inefficiencies in pricing and a more volatile public price for our securities in the near future than in connection with an underwritten initial public offering.

If our performance does not meet market expectations, the price of our securities may decline.

If our performance does not meet market expectations, the price of our Common Shares may decline. In addition, even if an active market for our Common Shares develops and continues, the trading price of our Common Shares could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Prior to the Business Combination, there was not a public market for our Common Shares, and trading in our Common Shares was not active. Any of the factors listed below could have a material adverse effect on the price of our Common Shares.

Factors affecting the trading price of our Common Shares may include:

- actual or anticipated fluctuations in our quarterly and annual financial results or the quarterly and annual financial results of companies perceived to be similar to it;
- changes in the market's expectations about operating results;
- our operating results failing to meet market expectations in a particular period;
- a Vant's operating results failing to meet market expectations in a particular period, which could impact the market prices of shares of a public Vant or the valuation of a private Vant, and in turn adversely impact the trading price of our Common Shares;
- the results of clinical trials or pre-clinical studies conducted by us and the Vants;
- changes in financial estimates and recommendations by securities analysts concerning us, the Vants or the biopharmaceutical industry and market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- changes in laws and regulations affecting our and the Vants' businesses;

- commencement of, or involvement in, litigation involving MAAC or us;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- the volume of our Common Shares available for public sale, which may be limited due to, among other reasons, the extent of redemptions by MAAC stockholders in connection with the consummation of the Business Consummation and the relatively limited free float of our Common Shares, particularly prior to the expiration of the lock-up provisions described elsewhere in this prospectus;
- any significant change in our board of directors or management;
- sales of substantial amounts of our Common Shares directors, executive officers or significant shareholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may depress the market price of our Common Shares irrespective of our or the Vants' operating performance. The stock market in general has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of our securities, may not be predictable. A loss of investor confidence in the market for companies engaging in digital payments or the stocks of other companies which investors perceive to be similar to us could depress our stock price regardless of our business, prospects, financial conditions or results of operations. A decline in the market price of our Common Shares also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

We have and will continue to incur increased costs as a result of operating as a public company and our management has and will continue to devote a substantial amount of time to new compliance initiatives.

As a public company, we have and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. In addition, we expect to record incremental share-based compensation expense in connection with the consummation of the Business Combination.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and forced us to accept reduced policy limits. We cannot predict or estimate the amount or timing of additional costs we have and will continue to incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.

As a public company, we are required to provide management's attestation on internal controls as required under Section 404(a) of the Sarbanes-Oxley Act. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us as a privately-held company. If we are not successful in implementing the additional requirements of Section 404(a)

in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

Failure to properly implement internal controls on a timely basis may lead to the identification of one or more material weaknesses or control deficiencies in the future, which may prevent us from being able to report our financial results accurately on a timely basis or help prevent fraud, and could cause our reported financial results to be materially misstated and result in the loss of investor confidence or delisting and cause the market price of our Common Shares to decline. If we have material weaknesses in the future, it could affect the financial results that we report or create a perception that those financial results do not fairly state our financial position or results of operations. Either of those events could have an adverse effect on the value of our Common Shares.

Further, even if we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our results of operations or cause us to fail to meet our future reporting obligations.

Changes in laws or regulations, or a failure to comply with any laws and regulations, may adversely affect our business, investments and results of operations.

We are subject to laws and regulations enacted by national, regional and local governments. In particular, we will be required to comply with certain SEC and other legal requirements. Compliance with, and monitoring of, applicable laws and regulations may be difficult, time consuming and costly. Those laws and regulations and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with applicable laws or regulations, as interpreted and applied, could have a material adverse effect on our business and results of operations.

Anti-takeover provisions in our memorandum of association and bye-laws and under Bermuda law could delay or prevent a change in control, limit the price investors may be willing to pay in the future for our Common Shares and could entrench management.

Our memorandum of association and bye-laws contain provisions that could make it more difficult for a third-party to acquire us without the consent of our board of directors. These provisions provide for:

- a classified board of directors with staggered three-year terms;
- the ability of our board of directors to determine the powers, preferences and rights of preference shares and to cause us to issue the preference shares without shareholder approval;
- the ability of our board of directors to prevent the transfer of capital stock, or the exercise of rights with respect to our capital stock, if the effect of such transfer or exercise of rights would result in a shareholder holding more than 9.9% of the total issued and outstanding shares of our capital stock on a fully diluted basis; and
- requiring advance notice for shareholder proposals and nominations and placing limitations on convening shareholder meetings.

These provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors of your choosing and cause us to take corporate actions other than those you desire, any of which could harm our share price.

Our largest shareholders and certain members of our management own a significant percentage of our Common Shares and are able to exert significant control over matters subject to shareholder approval.

Our founder and certain of our largest shareholders hold a significant percentage of our Common Shares. As a result, these holders have the ability to substantially influence us and exert significant control through this ownership position and, in the case of certain holders, service on our board of directors. For example, these holders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. These holders' interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as these holders continue to own a significant amount of our equity, they will continue to be able to strongly influence and effectively control our decisions.

Future sales and issuances of our or the Vants' equity securities or rights to purchase equity securities, including pursuant to our or the Vants' equity incentive and other compensatory plans, will result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We and the Vants will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, including in our subsidiaries, our shareholders may experience substantial dilution. We or the Vants may sell Common Shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Common Shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. In addition, new investors could gain rights superior to our existing shareholders.

Pursuant to our 2021 Equity Incentive Plan (the "2021 EIP"), we are authorized to grant options and other share-based awards to our employees, directors and consultants. The aggregate number of shares initially reserved for issuance under the 2021 EIP will be increased annually on the first day of each fiscal year during the term of the plan in an amount equal to the lesser of (i) 5% of the number of our Common Shares outstanding as of the day of the immediately preceding fiscal year and (ii) such number of our Common Shares as determined by our board of directors in its discretion. As a result of this annual increase, or if our board of directors elects in the future to make any additional increase in the number of shares available for future grant under the 2021 EIP, and if our shareholders approve of any such additional increase, our shareholders may experience additional dilution, and our share price may fall.

Issuance of options and other share-based awards pursuant to equity incentive plans at the Vants may indirectly have a similar effect of diluting your ownership in us since a portion of the value of our Common Shares is tied to the value of the Vants, which would be diluted in the event of a grant of options or other similar equity grants to the employees of the Vants.

If securities analysts publish negative evaluations of our shares, the price of our Common Shares could decline.

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. If any of the analysts who may cover us change their recommendation regarding our Common Shares adversely, or provide more favorable relative recommendations about its competitors, the price of our Common Shares would likely decline. If any analyst who may cover us were to cease coverage or fail to regularly publish reports, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Our founder and certain of our largest shareholders will own a substantial portion of our Common Shares. As a result, there may be limited liquidity for our Common Shares.

Our founder and certain of our largest shareholders hold a significant percentage of our Common Shares. Such shareholders are subject to certain lock-up arrangements and as a result there may initially be limited liquidity in the trading market for our Common Shares. In addition, even once the applicable lock-up periods expire, the liquidity for our Common Shares may remain limited given the substantial holdings of such shareholders, which could make the price of our Common Shares more volatile and may make it more difficult for investors to buy or sell large amounts of our Common Shares.

Because there are no current plans to pay cash dividends on our Common Shares for the foreseeable future, you may not receive any return on investment unless you sell our Common Shares for a price greater than that which you paid for it.

Our may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our Common Shares unless you sell your shares of for a price greater than that which you paid for them.

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are an exempted company limited by shares incorporated under the laws of Bermuda. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the U.S., against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Bermuda law differs from the laws in effect in the U.S. and may afford less protection to our shareholders.

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, (the “Companies Act”) which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal or would result in the violation of the company’s memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder will waive any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the U.S., particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the U.S.

There are regulatory limitations on the ownership and transfer of our Common Shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our Common Shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes Nasdaq. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our Common Shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the Nasdaq or another appointed stock exchange.

We may become subject to unanticipated tax liabilities and higher effective tax rates.

We are incorporated under the laws of Bermuda. We are centrally managed and controlled in the U.K., and under current U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, and subject to U.K.'s controlled foreign company rules, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could materially adversely affect our results of operations.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

We are incorporated under the laws of Bermuda. We currently have subsidiaries in the U.S., U.K., Switzerland, China and certain other jurisdictions. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer

prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable taxing authorities. If taxing authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require it to adjust its transfer prices and thereby reallocate its income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If taxing authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase its consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. We continue to assess the impact of such changes in tax laws and interpretations on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda, China and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in U.S. generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

The IRS may not agree that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes.

Under current U.S. federal income tax law, a corporation generally will be considered to be a U.S. corporation for U.S. federal income tax purposes only if it is created or organized in the United States or under the law of the United States or of any State. Accordingly, under generally applicable U.S. federal income tax rules, we, while we were not created or organized in the United States or under the law of the United States or of any State but is instead a Bermuda incorporated entity and tax resident of the U.K., would generally be classified as a non-U.S. corporation. Section 7874 of the Code and the Treasury regulations promulgated thereunder, however, contain specific rules that may cause a non-U.S. corporation to be treated as a U.S. corporation for U.S. federal income tax purposes. If it were determined that we are treated as a U.S. corporation for U.S. federal income tax purposes under Section 7874 of the Code and the Treasury regulations promulgated thereunder, we would be liable for U.S. federal income tax on our income just like any other U.S. corporation and certain distributions made by us to our shareholders that are not "U.S. Holders" of us would be subject to U.S. withholding tax. We believe that we should not be treated as a U.S. corporation for U.S. federal income tax purposes under Section 7874 of the Code. However, the interpretation of Treasury regulations relating to the required ownership of us is subject to uncertainty and there is limited guidance regarding their application. Accordingly, there can be no assurance that the IRS will not take a contrary position to those described above or that a court will not agree with a contrary position of the IRS in the event of litigation. You are urged to consult your tax advisor to determine the tax consequences if the classification of us as a non-U.S. corporation is not respected.

U.S. holders that own 10% or more of the combined voting power or value of our Common Shares may suffer adverse tax consequences because we and our non-U.S. subsidiaries may be characterized as "controlled foreign corporations" ("CFCs"), under Section 957(a) of the Code.

A non-U.S. corporation is considered a CFC if more than 50% of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by U.S. shareholders (U.S. persons who own stock representing 10% or more of the combined voting power or value of all outstanding stock of such non-U.S. corporation) on any day during the taxable year of such non-U.S. corporation. Certain U.S. shareholders of a CFC generally are required to include currently in gross income such shareholders' share of the CFC's "Subpart F income," a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such U.S. shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

We believe that we will not be classified as a CFC in the current taxable year. However, it is possible that our non-U.S. subsidiaries could be classified as CFCs in the current taxable year. For U.S. holders who hold 10% or more of the combined voting power or value of our Common Shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the IRS. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the combined voting power or value of our Common Shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing of our Common Shares.

U.S. holders of our Common Shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the average quarterly value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company (a "PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our Common Shares may suffer adverse tax consequences, including having gains realized on the sale of our Common Shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our Common Shares by individuals who are U.S. holders, and having interest charges apply to certain distributions by us and the proceeds of sales or other dispositions of our Common Shares that result in a gain to the U.S. holder. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset. If we are a CFC (determined by disregarding certain downward attribution rules) and not publicly traded for the relevant taxable year, however, the test shall be applied based on the adjusted basis of our assets.

Recently adopted Treasury regulations (the "New Regulations"), modify certain of the rules described above. Such modifications include, for example, permitting asset value to be determined more frequently than on a quarterly basis and treating a non-U.S. corporation as publicly traded for a taxable year if the stock of such corporation is publicly traded, other than in de minimis quantities, for at least twenty trading days during such taxable year.

The New Regulations generally apply to taxable years of shareholders beginning on or after January 14, 2021. A shareholder, however, may choose to apply such rules for any open taxable year beginning before January 14, 2021, provided that, with respect to a non-U.S. corporation being tested for PFIC status, the shareholder consistently applies certain of the provisions of the New Regulations and certain other Treasury regulations for such year and all subsequent years. Investors who are U.S. holders should consult their own tax advisors regarding the impact and applicability of the New Regulations.

Because our Common Shares should be considered to be "publicly traded" for the current taxable year that ends on March 31, 2022, we should apply the 50% passive asset test using the fair market value of our assets. This determination, however, is subject to uncertainty. In addition, our status may also depend, in part, on how quickly we utilize our cash on-hand and cash from future financings in our business.

Based on the foregoing, with respect to the taxable year that ended on March 31, 2021, we believe that we were not a PFIC (based in part on our belief that we were not classified as a CFC in the taxable year that ended on March 31, 2021) and presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill and intangible property, and the expected nature and composition of our income and assets. However, our status as a PFIC is a fact-intensive determination made on an annual basis, and we cannot provide any assurances regarding our PFIC status for the current or future taxable years. Our U.S. counsel expresses no opinion with respect to our PFIC status for the current or future taxable years. We will determine our PFIC status for each taxable year and make such determination available to U.S. holders.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and

arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC in the current and future taxable years. In addition, recently finalized U.S. Treasury regulations, of which we are continuing to assess the impact, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

USE OF PROCEEDS

Any sales of Common Shares by the Holders pursuant to this prospectus will be solely for the Holders' respective accounts. The Company will not receive any proceeds from any such sales.

The Holders will pay any underwriting fees, discounts and selling commissions incurred by such Holders in connection with any sale of their Common Shares. The Company will bear all other costs, fees and expenses incurred in effecting the registration of the Common Shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of counsel and independent registered public accountants.

DETERMINATION OF OFFERING PRICE

We cannot currently determine the price or prices at which Common Shares may be sold by the Holders under this prospectus.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

Market Information

The Common Shares are currently listed on The Nasdaq Global Market under the symbol “ROIV.” As of December 10, 2021, there were 216 holders of record of our Common Shares.

Dividend Policy

We have not declared or paid any dividends on our Common Shares to date. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of Roivant's financial condition and results of operations should be read in conjunction with Roivant's (1) unaudited condensed consolidated financial statements and notes to those statements included elsewhere in this prospectus and (2) audited consolidated financial statements and notes to those statements included elsewhere in this prospectus. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Roivant's actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. Please see "Cautionary Statement Regarding Forward-Looking Statements" and "Risk Factors." Our fiscal year ends on March 31 and our fiscal quarters end on June 30, September 30 and December 31.

Overview

We are building the next-generation "big pharma" company, organized to harness modern technologies and the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity.

We are a diverse team of experienced drug developers, scientists, physicians, company builders, data scientists and engineers, biopharma investors, physicists and business development professionals dedicated to improving the lives of patients. At Roivant, we combine our team's extensive experience and multi-disciplinary expertise with innovative technologies to identify and advance potentially transformative medicines.

We deploy a hypothesis-driven approach to identify novel or clinically-validated targets and biological pathways in areas of high unmet medical need. We then seek to acquire, in-license or discover promising drug candidates against those targets or pathways. Our small molecule discovery engine is powered by a unique combination of leading computational physics and machine learning ("ML") capabilities for in silico drug design.

We develop drug candidates in subsidiary companies we call "Vants" with a distinct approach to sourcing talent, aligning incentives and deploying technology. Each of our Vant teams is built with deep relevant expertise to promote successful execution of our development strategy. Our Vants continue to benefit from the support of our platform and technologies that are built to address inefficiencies in the drug discovery, development and commercialization process.

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology, hematology and oncology, and modalities, including biologics, topicals, gene therapies and bifunctional small molecules. We currently have 14 Vants and, together, we are advancing a deep and diversified pipeline of over 30 drug candidates. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately $940 million in the Public Vants as of September 30, 2021 (inclusive of the value of the Myovant Top-Up Shares). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

- conducted nine international Phase 3 trials, the last eight of which have been successful;
- consummated a $3 billion upfront partnership with Sumitomo;
- developed four drugs that received FDA approval after their transfer to Sumitomo;
- built a pipeline of over 30 drug candidates ranging from early discovery to registration;

- launched Roivant Discovery, our small molecule discovery engine comprising advanced computational physics and machine learning capabilities, integrated with an in-house wet lab facility; and
- created innovative software tools to optimize each stage of the drug discovery, development and commercialization process.

The following table summarizes our development-stage product candidate pipeline. In addition to the development-stage product candidates, we have active drug discovery projects in targets across oncology, immunology and neurology.

Product Candidate	Indication	Vant	Modality	Phase
Tapinarof	Psoriasis	Dermavant	Topical	Registration
Tapinarof	Atopic Dermatitis	Dermavant	Topical	Phase 3
Cerdulatinib	Vitiligo	Dermavant	Topical	Phase 2
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 2
Batoclimab	Warm Autoimmune Hemolytic Anemia	Immunovant	Biologic	Phase 2
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 2
ARU-1801	Sickle Cell Disease	Aruvant	Gene Therapy	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 1
LSVT-1701	Staph Aureus Bacteremia	Lysovant	Biologic	Phase 1
Cerdulatinib	Atopic Dermatitis	Dermavant	Topical	Phase 1
DMVT-504	Hyperhidrosis	Dermavant	Small Molecule	Phase 1
DMVT-503	Acne	Dermavant	Topical	Preclinical
ARU-2801	Hypophosphatasia	Aruvant	Gene Therapy	Preclinical
AFM32	Solid Tumors	Affivant	Biologic	Preclinical
CVT-TCR-01	Oncologic Malignancies	Cytovant	Cell Therapy	Preclinical

Note: All drugs in current pipeline are investigational and subject to health authority approval.

Our small molecule discovery engine powers *in silico* drug discovery, and includes the following key components:

- A quantum mechanics-based molecular dynamics software platform to predict the interactions, energies and conformational behavior of targets and generate novel drug candidates;
- A supercomputing cluster composed of over 600 graphics processing units;
- A suite of degrader-specific ML tools;
- A wet lab fully equipped for synthetic chemistry, crystallography, biophysics, biochemistry and biology.

The following table summarizes our ownership of certain subsidiary companies and affiliates as of September 30, 2021.

	Roivant Ownership	
Vant	Basic[1]	Fully Diluted[2]
Dermavant	100%	85%
Immunovant	64%[3]	59%[3]
Aruvant	88%	79%
Proteovant	60%	60%
Lysovant	100%	99%
Kinevant	88%	88%
Affivant	100%	99%
Cytovant	72%	68%
Arbutus	29%[3]	27%[3]
Sio Gene Therapies	25%[3]	24%[3]
Genevant	83%	67%
Lokavant	90%	84%
Datavant	*	*
Alyvant	97%	95%

Note: Excludes early-stage pipeline of protein degraders and inhibitors being developed through our small molecule discovery engine. All drugs in current pipeline are investigational and subject to health authority approval. Ownership figures as of September 30, 2021. Arbutus basic and fully diluted ownership includes the conversion of preferred shares held by Roivant into common shares, which was completed on October 18, 2021. Roivant ownership in Cytovant includes both direct and indirect ownership.

* In June 2021, Datavant entered into a definitive merger agreement to combine with Ciox Health. The transaction closed on July 27, 2021. The implied enterprise value of the combined company at the conversion price cap of the new preferred equity investment made concurrently with the closing of the merger was $7.0 billion. This enterprise value implies an equity value of $6.1 billion (after netting out approximately $900 million of debt and other adjustments). No assurance can be given that the implied enterprise or equity value is an accurate reflection of the value of the combined business at closing or in the future. At closing of the merger and assuming a $7.0 billion enterprise value, Roivant's ongoing, fully diluted equity ownership in the combined entity was approximately 12% (without giving effect to certain liquidation preferences held by the preferred equity shareholders).

1. Basic refers to Roivant's percentage ownership of the issued and outstanding shares of the entity.
2. Fully diluted refers to Roivant's percentage ownership of all outstanding equity interests, whether vested or unvested, of the entity.
3. Denotes entities that are publicly traded.

Through continued investment in our model, we believe we are well-positioned to advance our current pipeline through regulatory approval and commercialization, expand our pipeline through novel drug discovery and in-licensing and acquisition transactions, and execute on our vision of transforming the delivery of healthcare to patients.

We have a robust calendar of potential near-term catalysts, including the items set forth below. In addition, we plan to in-license multiple potentially category-leading drugs per year.

Vant	Catalyst	Expected Timing
Dermavant	Tapinarof NDA filing in psoriasis	Mid-2021 ✓
	Tapinarof Phase 3 initiation in atopic dermatitis	2H 2021 ✓
	FDA approval decision on tapinarof for psoriasis	2Q 2022
	Topline data from tapinarof Phase 3 trials in atopic dermatitis	1H 2023
Immunovant	Initiate pivotal trial in MG	1H 2022
	Reinitiate program in TED	TBA
	Reinitiate program in WAIHA	TBA
	Announce at least two new indications for batoclimab	2H 2022
Aruvant	First patient dosed with updated ARU-1801 manufacturing process	2H 2021 ✓
	Additional clinical data from ARU-1801 Phase 1/2	2H 2021 ✓
	ARU-1801 Phase 3 initiation	1H 2023
Kinevant	Namilumab Phase 2 initiation in sarcoidosis	1H 2022
Lysovant	LSVT-1701 MAD initiation	1H 2022
Proteovant	Phase 1 initiation for first degrader candidate	2022
Roivant / Proteovant	Multiple additional degrader candidates entering IND-enabling studies each year	Starting 2022

Note: References are to calendar years. All catalyst timings are based on current expectations and, where applicable, contingent on FDA feedback, and may be subject to change.

Recent Developments

- **Roivant:** Roivant closed its business combination with Montes Archimedes Acquisition Corp. and concurrent PIPE financing, and Roivant began trading on Nasdaq under the ticker “ROIV.” Roivant also announced the appointment of its new Chief Financial Officer, Richard Pulik, who previously served as the Global Head of Business Development & Licensing and Portfolio Management, Oncology at Novartis.
- **Dermavant:** At the 30th EADV Virtual Congress, Dermavant presented final results from the Phase 3 PSOARING 3 long-term extension study of tapinarof in patients with plaque psoriasis. The study results demonstrated that tapinarof was generally well tolerated long term, with a safety profile consistent with the pivotal studies and previously reported interim analysis of data from PSOARING 3. The study demonstrated a high rate of complete disease clearance, with 58.2% of patients who entered the study with a PGA score ³2 achieving a PGA score of 0 or 1. The study also demonstrated improved and durable results for up to 52 weeks and a median remittive effect off-therapy of approximately four months for patients entering with a PGA score of 0.
- **Aruvant:** At Roivant’s Annual R&D Day, Aruvant released clinical data from the third and fourth patients dosed in its ongoing Phase 1/2 trial of ARU-1801 in sickle cell disease. These patients, the first to be dosed with Aruvant’s updated manufacturing process, have had zero vaso-occlusive events 18 and 12 months after dosing, respectively. Punam Malik, M.D., Director of the Cincinnati Comprehensive Sickle Cell Center and Program Leader of the Hematology and Gene Therapy Program at the Cincinnati Children’s Hospital Medical Center, presented data highlighting the clinically meaningful reduction in vaso-oclusive events of participants in the Phase 1/2 trial and the unique attributes that contribute to the potency of ARU-1801 at the American Society of Hematology (ASH) Annual Meeting on December 13, 2021.

- **Sio Gene Therapies:** Sio Gene Therapies announced positive interim safety and biomarker data from its ongoing Phase 1/2 clinical trial of AXO-AAV-GM1 in GM1 gangliosidosis, showing consistent dose-dependent improvements across biomarker measures and no overt disease progression in six out of seven patients treated across low- and high-dose cohorts.
- **Acquisition of Silicon Therapeutics:** In November 2021, Roivant paid the previously-disclosed $100.0 million second tranche of consideration due in connection with Roivant's March 2021 acquisition of Silicon Therapeutics. This second tranche of consideration comprised (i) a payment of $50.0 million in cash and (ii) the issuance of 6,348,057 Common Shares.
- **Immunovant:** In December 2021, Immunovant announced that it had achieved alignment with the FDA Division of Neurology 1 to move forward in myasthenia gravis ("MG"). Immunovant plans to start its Phase 3 study for batoclimab in MG in the first half of calendar year 2022.

Business Combination

On September 30, 2021, in accordance with the Business Combination Agreement, as amended (the "Business Combination Agreement"), we completed our previously announced business combination (the "Business Combination") with MAAC, through the merger of our wholly-owned subsidiary, Rhine Merger Sub, Inc., with MAAC (the "Merger"), with MAAC surviving the Merger as our wholly owned subsidiary. As MAAC does not represent a business for accounting purposes and its primary asset represents cash and cash equivalents, the Business Combination was treated as an equity contribution in exchange for the issuance of RSL shares. The net assets of MAAC were stated at historical cost, with no goodwill or other intangible assets recorded.

Impact of COVID-19

We have been actively monitoring the impact of the COVID-19 pandemic on our employees and our business. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for our employees in March 2020 and our workforce continues to primarily work remotely.

The COVID-19 pandemic has had a variable impact on our clinical trials by disrupting certain study sites. In the conduct of our business activities, we continue to take actions designed to protect the safety and well-being of our patients and employees. Although some of our clinical development timelines have been impacted by delays related to the COVID-19 pandemic, we have not experienced material financial impacts on our business and operations as a result of the COVID-19 pandemic. However, the impact on our future results will largely depend on future developments related to COVID-19, which are highly uncertain and cannot be predicted with confidence, such as the emergence of new variants, the ultimate duration and spread of the outbreak, the continuing impact of the COVID-19 pandemic on financial markets and the global economy, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain, treat, and prevent the disease, including the availability and effectiveness of vaccines.

For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled "Risk Factors" included elsewhere in this prospectus.

Components of Results of Operations

Revenue, net

We have not generated any revenues to date from the sale of our product candidates and do not anticipate generating any revenues from the sale of product candidates unless and until we successfully complete development and obtain regulatory approval to market our product candidates. Our revenue to date primarily includes the recognition of upfront payments received in connection with license agreements. Revenue is also generated by subscription and service-based fees. Our revenue recognized from inception to date has not been significant.

Cost of revenues

Our cost of revenues primarily relates to subscription and service-based revenue recognized for the use of technology developed and consists primarily of employee, hosting, and third-party data costs. Our cost of revenues has not been significant to date.

Research and development expenses

Research and development expenses consist mainly of costs incurred in connection with the discovery and development of our product candidates. Research and development expenses primarily include the following:

- Program-specific costs, including:
  - direct third-party costs, which include expenses incurred under agreements with CROs and CMOs, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, and any other third-party expenses directly attributable to the development of our product candidates; and
  - payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.
- Consideration for the purchase of in-process research and development ("IPR&D") through asset acquisitions and license agreements, including:
  - cash upfront payments;
  - shares and other liability instruments issued; and
  - fair value of future contingent consideration payments.
- Unallocated internal costs, including:
  - employee-related expenses, such as salaries, share-based compensation, and benefits, for research and development personnel; and
  - other expenses, including consulting costs, that are not allocated to a specific program.

Research and development activities, including asset acquisitions and license agreements, will continue to be central to our business model. We anticipate that our research and development expenses will increase for the foreseeable future as we advance our product candidates through preclinical studies and clinical trials, as well as acquire new product candidates. In addition, we expect our research and development expenses to increase in the future, including as a result of our small molecule discovery engine ("Roivant Discovery"), comprising advanced computational physics and machine learning capabilities, integrated with an in-house wet lab facility. Research and development expenses will also be driven by the number of drug candidates from Roivant Discovery that we advance through preclinical studies and clinical trials. We expect higher employee-related expenses, including higher share-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity.

The duration, costs and timing of preclinical studies and clinical trials of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of our product candidates, and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;

- the number of doses that patients receive;
- the countries in which the trials are conducted;
- our ability to secure and leverage adequate CRO support for the conduct of clinical trials;
- our ability to establish an appropriate safety and efficacy profile for our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the significant and changing government regulation and regulatory guidance;
- our ability to establish clinical and commercial manufacturing capabilities, or make arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations due to the COVID-19 pandemic; and
- our ability to maintain a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

In addition, the probability of success for our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability.

General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses for general and administrative personnel, including those responsible for the identification and acquisition or in-license of new drug candidates as well as for overseeing Vant operations and facilitating the use of our platform and technologies at Vants. General and administrative expenses also consist of legal and accounting fees, consulting services and other operating costs relating to corporate matters and daily operations. General and administrative expenses also include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates along with costs incurred relating to the integration of new technologies.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, potential commercialization efforts, and increased costs associated with being a public company. These increases will likely include additional costs related to the hiring of new personnel, including higher share-based compensation expenses, and fees to outside consultants, as well as other expenses. As a public company, we anticipate incurring expenses related to maintaining compliance with the rules and regulations promulgated by the SEC, the applicable Nasdaq listing rules and the requirements of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”). If any of our current or future product candidates receives regulatory approval in the U.S. or another jurisdiction, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Change in fair value of investments

Change in fair value of investments includes the unrealized loss (gain) on equity investments in publicly-traded companies, including Sio Gene Therapies Inc. (“Sio”) and Arbutus Biopharma Corporation (“Arbutus”), as well as our equity investment in Heracles Parent, L.L.C., the parent entity of the Datavant business (“Datavant”), following Datavant’s merger with a wholly-owned subsidiary of Heracles Parent, L.L.C., the parent company of CIOX Health (the “Datavant Merger”) in July 2021 at which point our minority equity interest in Datavant became subject to the equity method of accounting. We have elected the fair value option to account for these investments.

Gain on sale of investment

Gain on sale of investment resulted from the Datavant Merger in July 2021. Prior to the Datavant Merger, our investment in Datavant was accounted for using the measurement alternative to fair value. At closing of the Datavant Merger, we received approximately $320 million in cash and a minority equity interest in the combined company, which became subject to the equity method of accounting. We recognized a gain as a result of this transaction.

Change in fair value of debt and liability instruments

Change in fair value of debt and liability instruments primarily includes the unrealized loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including debt issued by a wholly-owned subsidiary of Dermavant to NovaQuest Co-Investment Fund VIII, L.P. (the "NovaQuest Facility"), and other liability instruments, including options granted to Sumitomo to purchase our ownership interests in certain subsidiaries (the "Sumitomo Options") before the termination of those options in June 2021.

Gain on termination of Sumitomo Options

Gain on termination of Sumitomo Options resulted from the completion of transactions contemplated by an Asset Purchase Agreement entered into with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. ("SPC") in May 2021. The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire our ownership interest in certain subsidiaries; (ii) we transferred and assigned to SPC all of our intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively "Greater China"), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) Sumitomo agreed to pay us $5.0 million in cash; and (iv) Sumitomo entered into an agreement with us to pursue future collaborations with Genevant. The Company received the cash payment, net of certain withholding taxes, in August 2021.

Other expense (income), net

Other expense (income), net consists of losses from our equity method investment, interest income on our cash and cash equivalents, interest expense resulting from interest accrued on long-term debt and the amortization of debt discount and issuance costs, and other miscellaneous income.

Income tax expense

Income tax expense is recorded for the jurisdictions in which we do business. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that our deferred tax assets will be realizable. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Net loss attributable to noncontrolling interests

Net loss attributable to noncontrolling interests consists of the portion of net loss of those consolidated entities that is not allocated to us. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by the net loss of our consolidated entities and changes in ownership percentages.

Results of Operations

Comparison of the three and six months ended September 30, 2021 and 2020

The following table sets forth our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Revenue, net	$ 13,987	$ 1,323	$ 12,664
Operating expenses:			
Cost of revenues	6,381	715	5,666
Research and development	254,259	97,409	156,850
General and administrative	437,776	59,740	378,036
Total operating expenses	698,416	157,864	540,552
Loss from operations	(684,429)	(156,541)	(527,888)
Change in fair value of investments	(32,273)	(84,297)	52,024
Gain on sale of investment	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	13,145	10,148	2,997
Gain on consolidation of unconsolidated entity	—	(28,848)	28,848
Other expense (income), net	3,692	(757)	4,449
Loss before income taxes	(225,239)	(52,787)	(172,452)
Income tax expense	401	711	(310)
Net loss	(225,640)	(53,498)	(172,142)
Net loss attributable to noncontrolling interests	(17,159)	(18,100)	941
Net loss attributable to Roivant Sciences Ltd.	$(208,481)	$ (35,398)	$(173,083)

The following table sets forth our results of operations for the six months ended September 30, 2021 and 2020:

	Six Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Revenue, net	$ 21,722	$ 2,899	$ 18,823
Operating expenses:			
Cost of revenues	7,123	895	6,228
Research and development	332,885	156,143	176,742
General and administrative	520,530	116,855	403,675
Total operating expenses	860,538	273,893	586,645
Loss from operations	(838,816)	(270,994)	(567,822)
Change in fair value of investments	(23,654)	(125,445)	101,791
Gain on sale of investment	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	17,730	27,273	(9,543)
Gain on termination of Sumitomo Options	(66,472)	—	(66,472)
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	(115,364)	115,364
Other expense, net	3,558	2,085	1,473
Loss before income taxes	(326,224)	(59,543)	(266,681)
Income tax expense	494	1,932	(1,438)
Net loss	(326,718)	(61,475)	(265,243)
Net loss attributable to noncontrolling interests	(36,054)	(22,834)	(13,220)
Net loss attributable to Roivant Sciences Ltd.	$(290,664)	$ (38,641)	$(252,023)

Variance analysis for three and six months ended September 30, 2021 and 2020

Revenue, net

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Revenue, net	$ 13,987	$ 1,323	$ 12,664	$ 21,722	$ 2,899	$ 18,823

Revenue, net increased by $12.7 million to $14.0 million for the three months ended September 30, 2021 compared to $1.3 million for the three months ended September 30, 2020, primarily due to the recognition of upfront payments received in connection with license agreements and sales of clinical product to Japan Tobacco Inc. pursuant to the collaboration and license agreement entered into with Dermavant. Revenue generated was not significant in either period presented.

Revenue, net increased by $18.8 million to $21.7 million for the six months ended September 30, 2021 compared to $2.9 million for the three months ended September 30, 2020, primarily due to the recognition of upfront payments received in connection with license agreements and sales of clinical product to Japan Tobacco Inc. pursuant to the collaboration and license agreement entered into with Dermavant. Revenue generated was not significant in either period presented.

Cost of revenues

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Cost of revenues	$6,381	$ 715	$5,666	$ 7,123	$ 895	$6,228

Cost of revenues increased by $5.7 million to $6.4 million for the three months ended September 30, 2021 compared to $0.7 million for the three months ended September 30, 2020, primarily due to cost of revenues associated with the sales of clinical product to Japan Tobacco Inc. pursuant to the collaboration and license agreement entered into with Dermavant. Cost of revenues was not significant in either period presented.

Cost of revenues increased by $6.2 million to $7.1 million for the six months ended September 30, 2021 compared to $0.9 million for the six months ended September 30, 2020, primarily due to cost of revenues associated with the sales of clinical product to Japan Tobacco Inc. pursuant to the collaboration and license agreement entered into with Dermavant. Cost of revenues was not significant in either period presented.

Research and development expenses

For the three months ended September 30, 2021 and 2020, our research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Program-specific costs:			
Tapinarof (Dermavant Sciences Ltd.)	$ 67,656	$ 8,905	$ 58,751
Batoclimab (Immunovant, Inc.)	13,479	8,465	5,014
ARU-1801 (Aruvant Sciences Ltd.)	7,362	8,187	(825)
Gimsilumab (Kinevant Sciences Ltd.)	1,384	7,178	(5,794)
Other program-specific costs	22,665	5,714	16,951
Total program-specific costs	112,546	38,449	74,097
Consideration for the purchase of IPR&D through asset acquisitions and license agreements	82,107	45,339	36,768
Unallocated internal costs:			
Share-based compensation	28,157	1,887	26,270
Personnel-related expenses	23,760	11,386	12,374
Other expenses	7,689	348	7,341
Total research and development expenses	$254,259	$97,409	$156,850

For the six months ended September 30, 2021 and 2020, our research and development expenses consisted of the following:

	Six Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Program-specific costs:			
Tapinarof (Dermavant Sciences Ltd.)	$ 77,413	$ 17,319	$ 60,094
Batoclimab (Immunovant, Inc.)	27,167	22,858	4,309
ARU-1801 (Aruvant Sciences Ltd.)	9,751	11,540	(1,789)
Gimsilumab (Kinevant Sciences Ltd.)	3,453	19,503	(16,050)
Other program-specific costs	42,777	14,811	27,966
Total program-specific costs	160,561	86,031	74,530
Consideration for the purchase of IPR&D through asset acquisitions and license agreements	82,107	45,339	36,768
Unallocated internal costs:			
Share-based compensation	29,772	3,006	26,766
Personnel-related expenses	45,852	20,153	25,699
Other expenses	14,593	1,614	12,979
Total research and development expenses	$332,885	$156,143	$176,742

Research and development expenses increased by $156.9 million to $254.3 million for the three months ended September 30, 2021 compared to $97.4 million for the three months ended September 30, 2020, primarily due to increases in program-specific costs of $74.1 million, consideration for the purchase of IPR&D through asset acquisitions and license agreements of $36.8 million, share-based compensation of $26.3 million, and personnel-related expenses of $12.4 million.

The increase of $74.1 million in program-specific costs was primarily due to an increase of $58.8 million for Dermavant's tapinarof program, largely resulting from a one-time milestone expense of C$50.0 million (approximately $39 million) due to the achievement of a development milestone and purchases of approximately $22.3 million of clinical product and commercial active pharmaceutical ingredient. Additionally, other program-specific costs increased by $17.0 million.

The increase of $36.8 million in consideration for the purchase of IPR&D was primarily due to consideration of $82.1 million relating to an asset acquisition completed by a newly-formed subsidiary.

The increase of $26.3 million in share-based compensation expense was primarily due to the achievement of the liquidity event vesting condition for restricted stock units, performance options, and capped value appreciation rights upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $22.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met.

The increase of $12.4 million in personnel-related expenses is partially driven by additional headcount to support drug discovery efforts using our computational discovery technology and targeted protein degradation platform, following the acquisition of Silicon Therapeutics ("SiTX") in March 2021 and Oncopia Therapeutics, Inc. ("Oncopia") in November 2020.

Research and development expenses increased by $176.7 million to $332.9 million for the six months ended September 30, 2021 compared to $156.1 million for the six months ended September 30, 2020, primarily due to

increases in program-specific costs of $74.5 million, consideration for the purchase of IPR&D through asset acquisitions and license agreements of $36.8 million, share-based compensation of $26.8 million, and personnel-related expenses of $25.7 million.

The increase of $74.5 million in program-specific costs was primarily due to an increase of $60.1 million for Dermavant's tapinarof program, largely resulting from a one-time milestone expense of C$50.0 million (approximately $39 million) due to the achievement of a development milestone and purchases of approximately $22.3 million of clinical product and commercial active pharmaceutical ingredient. Additionally, other program-specific costs increased by $28.0 million. These increases were partially offset by a decrease of $16.1 million for Kinevant Sciences Ltd.'s gimsilumab program primarily as a result of higher costs during the six months ended September 30, 2020 related to our study in COVID-19 Associated ARDS.

The increase of $36.8 million in consideration for the purchase of IPR&D was primarily due to consideration of $82.1 million relating to an asset acquisition completed by a newly-formed subsidiary.

The increase of $26.8 million in share-based compensation expense was primarily due to the achievement of the liquidity event vesting condition for restricted stock units, performance options, and capped value appreciation rights upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $22.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met.

The increase of $25.7 million in personnel-related expenses is partially driven by additional headcount to support drug discovery efforts using our computational discovery technology and targeted protein degradation platform, following the acquisition of SiTX in March 2021 and Oncopia in November 2020.

General and administrative expenses

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
General and administrative	$ 437,776	$ 59,740	$ 378,036	$ 520,530	$ 116,855	$ 403,675

General and administrative expenses increased by $378.0 million to $437.8 million for the three months ended September 30, 2021 compared to $59.7 million for the three months ended September 30, 2020. The increase was largely due to an increase in share-based compensation expense of $357.1 million primarily as a result of the achievement of the liquidity event vesting condition for restricted stock units, performance options, and capped value appreciation rights upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $350.0 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met.

General and administrative expenses increased by $403.7 million to $520.5 million for the six months ended September 30, 2021 compared to $116.9 million for the six months ended September 30, 2020. The increase was largely due to an increase in share-based compensation expense of $361.6 million primarily as a result of the achievement of the liquidity event vesting condition for restricted stock units, performance options, and capped value appreciation rights upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $350.0 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. Historically, we did not recognize share-based

compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met. Additionally, legal and other professional and consulting fees increased by $21.4 million in part to support our higher operating activities as we prepared to operate as a public company.

Change in fair value of investments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Change in fair value of investments	$(32,273)	$ (84,297)	$52,024	$(23,654)	$(125,445)	$101,791

Change in fair value of investments was an unrealized gain of $32.3 million and $84.3 million for the three months ended September 30, 2021 and 2020, respectively. The change of $52.0 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant following the completion of the Datavant Merger in July 2021.

Change in fair value of investments was an unrealized gain of $23.7 million and $125.4 million for the six months ended September 30, 2021 and 2020, respectively. The change of $101.8 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant following the completion of the Datavant Merger in July 2021.

Gain on sale of investment

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on sale of investment	$(443,754)	$ —	$ (443,754)	$ (443,754)	$—	$ (443,754)

Gain on sale of investment was $443.8 million for the three and six months ended September 30, 2021 due to the Datavant Merger in July 2021 at which point we received approximately $320 million in cash and a minority equity stake in the combined company. See “Components of Results of Operations—Gain on sale of investment” above for additional information.

Change in fair value of debt and liability instruments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Change in fair value of debt and liability instruments	$ 13,145	$ 10,148	$ 2,997	$ 17,730	$ 27,273	$ (9,543)

Change in fair value of debt and liability instruments was an unrealized loss of $13.1 million and $10.1 million for the three months ended September 30, 2021 and 2020, respectively. Change in fair value of debt and liability instruments for the three months ended September 30, 2021 primarily consisted of an unrealized loss of $13.0 million relating to the NovaQuest facility, which was largely due to the passage of time and increased probabilities of success as a result of advancement in the stage of development of the product candidate. Change in fair value of debt and liability instruments for the three months ended September 30, 2020 primarily consisted of an unrealized loss of $12.1 million relating to the NovaQuest Facility, which was largely due to a decrease in the discount rate.

Change in fair value of debt and liability instruments was an unrealized loss of $17.7 million and $27.3 million for the six months ended September 30, 2021 and 2020, respectively. Change in fair value of debt and liability instruments for the six months ended September 30, 2021 primarily consisted of an unrealized loss of $18.1 million relating to the NovaQuest facility, which was largely due to the passage of time and increased probabilities of success as a result of advancement in the stage of development of the product candidate. Change in fair value of debt and liability instruments for the six months ended September 30, 2020 primarily consisted of an unrealized loss of $30.0 million relating to the NovaQuest Facility, which was largely due to a decrease in the discount rate.

Gain on termination of Sumitomo Options

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on termination of Sumitomo Options	$—	$ —	$ —	$(66,472)	$—	$(66,472)

Gain on termination of Sumitomo Options was $66.5 million for the six months ended September 30, 2021 due to the completion of transactions contemplated by the Asset Purchase Agreement entered into with Sumitomo and SPC. See “Components of Results of Operations—Gain on termination of Sumitomo Options” above for additional information.

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	$—	$ (28,848)	$28,848	$ —	$(115,364)	$115,364

Gain on consolidation of unconsolidated entity was $28.8 million for the three months ended September 30, 2020 due to a gain of $28.8 million resulting from the remeasurement of our previously held interest in Genevant upon its consolidation in July 2020.

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity was $115.4 million for the six months ended September 30, 2020, primarily due to a gain of $86.5 million on the deconsolidation of Datavant in April 2020 and a gain of $28.8 million resulting from the remeasurement of our previously held interest in Genevant upon its consolidation in July 2020.

Other expense (income), net

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Other expense (income), net	$3,692	$ (757)	$4,449	$ 3,558	$ 2,085	$1,473

Other expense (income), net consisted of $3.7 million of other expense, net and $0.8 million of other income, net for the three months ended September 30, 2021 and 2020, respectively. Other expense (income), net was not significant in either period presented.

Other expense, net consisted of $3.6 million and $2.1 million of other expense, net for the six months ended September 30, 2021 and 2020, respectively. Other expense, net was not significant in either period presented.

Income tax expense

	Three Months Ended September 30,			Six Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(in thousands)			*(in thousands)*		
Income tax expense	$ 401	$ 711	$ (310)	$ 494	$ 1,932	$(1,438)

Income tax expense decreased by $0.3 million to $0.4 million for the three months ended September 30, 2021, compared to $0.7 million for the three months ended September 30, 2020. Income tax expense was not significant in either period presented and reflects the income tax expense computed in jurisdictions in which we operate.

Income tax expense decreased by $1.4 million to $0.5 million for the six months ended September 30, 2021, compared to $1.9 million for the six months ended September 30, 2020. Income tax expense was not significant in either period presented and reflects the income tax expense computed in jurisdictions in which we operate.

Comparison of the years ended March 31, 2021 and 2020

The following table sets forth our results of operations for the years ended March 31, 2021 and 2020:

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Revenue, net	$ 23,795	$ 67,689	$ (43,894)
Operating expenses:			
Cost of revenues	2,057	1,131	926
Research and development	832,758	263,217	569,541
General and administrative	259,878	335,766	(75,888)
Total operating expenses	1,094,693	600,114	494,579
Loss from operations	(1,070,898)	(532,425)	(538,473)
Change in fair value of investments	(95,533)	136,005	(231,538)
Change in fair value of debt and liability instruments	29,845	(13,722)	43,567
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(115,364)	(107,344)	(8,020)
Other expense, net	8,701	13,622	(4,921)
Loss from continuing operations before income taxes	(898,547)	(560,986)	(337,561)
Income tax expense	1,686	7,124	(5,438)
Loss from continuing operations, net of tax	(900,233)	(568,110)	(332,123)
Income from discontinued operations, net of tax	—	1,578,426	(1,578,426)
Net (loss) income	(900,233)	1,010,316	(1,910,549)
Net loss attributable to noncontrolling interests	(90,999)	(190,193)	99,194
Net (loss) income attributable to Roivant Sciences Ltd.	$ (809,234)	$1,200,509	$(2,009,743)

Variance analysis for years ended March 31, 2021 and 2020

Revenue, net

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Revenue, net	$ 23,795	$ 67,689	$(43,894)

Revenue, net decreased by $43.9 million to $23.8 million for the year ended March 31, 2021 compared to $67.7 million for the year ended March 31, 2020. The decrease was primarily driven by a nonrefundable, upfront payment of $60.0 million received by Dermavant during the year ended March 31, 2020 from Japan Tobacco Inc., parent company of Torii Pharmaceutical Co., Ltd., for the exclusive rights to develop, register, and market tapinarof in Japan, partially offset by $19.8 million of revenue generated by Genevant during the year ended March 31, 2021 following consolidation in July 2020. Revenue generated by subscription and service-based fees was not significant in either period presented.

Cost of revenues

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Cost of revenues	$ 2,057	$ 1,131	$ 926

Cost of revenues increased by $0.9 million to $2.1 million for the year ended March 31, 2021 compared to $1.1 million for the year ended March 31, 2020. Cost of revenues was not significant in either period presented and reflects cost of revenues generated by subscription and service-based fees.

Research and development expenses

For the years ended March 31, 2021 and 2020, our research and development expenses consisted of the following:

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Program-specific costs:			
IMVT-1401 (Immunovant, Inc.)	$ 49,236	$ 39,230	$ 10,006
Tapinarof (Dermavant Sciences Ltd.)	34,002	69,394	(35,392)
ARU-1801 (Aruvant Sciences Ltd.)	24,347	11,064	13,283
Gimsilumab (Kinevant Sciences Ltd.)	21,969	7,288	14,681
RVT-1601 (Respivant Sciences Ltd.)	6,784	16,935	(10,151)
AXO-LENTI-PD (Sio Gene Therapies, Inc.)	—	21,219	(21,219)
Other program-specific costs	29,790	32,402	(2,612)
Total program-specific costs	166,128	197,532	(31,404)
Consideration for the purchase of IPR&D through asset acquisitions and license agreements	591,916	10,250	581,666
Unallocated internal costs:			
Share-based compensation	22,637	7,738	14,899
Personnel-related expenses	45,646	33,865	11,781
Other expenses	6,431	13,832	(7,401)
Total research and development expenses	$832,758	$263,217	$569,541

Research and development expenses increased by $569.5 million to $832.8 million for the year ended March 31, 2021 compared to $263.2 million for the year ended March 31, 2020 primarily due to an increase of $581.7 million in consideration for the purchase of IPR&D through asset acquisitions and license agreements, partially offset by a decrease in program-specific costs of $31.4 million.

The increase of $581.7 million in consideration for the purchase of IPR&D was primarily due to multiple asset acquisitions and license agreements entered into during the year ended March 31, 2021, including consideration of $399.6 million attributed to IPR&D relating to the acquisition of the business of SiTX; consideration of $116.5 million relating to the stock purchase agreement to acquire Oncopia; $41.4 million attributed to IPR&D as part of the consolidation of Genevant, which was previously accounted for as an equity method investment; and consideration relating to the licensing and strategic collaboration agreement with Affimed N.V. (“Affimed”), pursuant to which Affimed received consideration that included $40.0 million in upfront cash and pre-paid research and development funding and $20.0 million of our Common Shares. During the year ended March 31, 2020, we made a one-time upfront payment of $10.0 million related to our multi-program license and collaboration agreement with Medigene AG.

The decrease of $31.4 million in program-specific costs was mainly due to a decrease of $35.4 million relating to Dermavant’s tapinarof program primarily as a result of the completion of two pivotal Phase 3 clinical trials, PSOARING 1 AND PSOARING 2, and a one-time milestone payment of C$30.0 million (approximately $23 million) made upon the achievement of a development milestone during the year ended March 31, 2020; decrease of $21.2 million relating to Sio’s AXO-LENTI-PD program as a result of the deconsolidation of Sio in February 2020; and decrease of $10.2 million for Respivant Sciences Ltd.’s (“Respivant”) RVT-1601 program as a result of its termination. These decreases were partially offset by increases of $14.7 million for Kinevant’s gimsilumab program, including $3.0 million resulting from the achievement of development milestones, $13.3 million for Aruvant’s ARU-1801 program, and $10.0 million for Immunovant’s IMVT-1401 program. These increases in program-specific costs were primarily due to increases in clinical development costs.

General and administrative expenses

	Years Ended March 31,		
	2021	2020	Change
		(in thousands)	
General and administrative	$259,878	$335,766	$(75,888)

General and administrative expenses decreased by $75.9 million to $259.9 million for the year ended March 31, 2021 compared to $335.8 million for the year ended March 31, 2020. The decrease was primarily due to decreases in personnel-related expenses of $38.5 million and professional and transaction fees of $27.9 million. The decrease in personnel-related expenses is partially driven by the deconsolidation of Sio in February 2020 and Datavant in April 2020.

Change in fair value of investments

	Years Ended March 31,		
	2021	2020	Change
		(in thousands)	
Change in fair value of investments	$(95,533)	$136,005	$(231,538)

Change in fair value of investments was an unrealized gain of $95.5 million and unrealized loss of $136.0 million for the years ended March 31, 2021 and 2020, respectively. The change of $231.5 million was primarily driven by changes in the share prices of Arbutus and Sio.

Change in fair value of debt and liability instruments

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Change in fair value of debt and liability instruments	$29,845	$(13,722)	$43,567

Change in fair value of debt and liability instruments was an unrealized loss of $29.8 million and unrealized gain of $13.7 million for the years ended March 31, 2021 and 2020, respectively. Change in fair value of debt and liability instruments for the year ended March 31, 2021 primarily consisted of an unrealized loss of $61.0 million relating to the NovaQuest Facility, partially offset by an unrealized gain of $33.5 million relating to the Sumitomo Options. Change in fair value of debt and liability instruments for the year ended March 31, 2020 primarily consisted of an unrealized gain of $9.9 million relating to the NovaQuest Facility and an unrealized gain of $3.2 million relating to the Sumitomo Options. Changes in the fair value of the NovaQuest Facility primarily resulted from updates to the estimated timing of amounts payable to NovaQuest and discount rates.

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	$(115,364)	$(107,344)	$(8,020)

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity was $115.4 million and $107.3 million for the years ended March 31, 2021 and 2020, respectively. Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity for the year ended March 31, 2021 primarily related to a gain of $86.5 million on the deconsolidation of Datavant in April 2020 and a gain of $28.8 million resulting from the remeasurement of our previously held interest in Genevant upon its consolidation in July 2020. Gain on deconsolidation of subsidiary was $107.3 million for the year ended March 31, 2020 due to the deconsolidation Sio in February 2020.

Other expense, net

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Other expense, net	$ 8,701	$ 13,622	$(4,921)

Other expense, net was $8.7 million and $13.6 million for the years ended March 31, 2021 and 2020, respectively. The change in other expense, net was primarily driven by reduced losses from our equity method investment in Genevant of $17.6 million incurred through July 2020 until we consolidated Genevant and lower interest expense of $4.9 million, partially offset by lower interest income of $16.6 million for the year ended March 31, 2021 as compared to the year ended March 31, 2020.

Income tax expense

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Income tax expense	$ 1,686	$ 7,124	$(5,438)

Income tax expense decreased by $5.4 million to $1.7 million for the year ended March 31, 2021, compared to $7.1 million for the year ended March 31, 2020. Income tax expense was not significant in either period presented and reflects the income tax expense computed in jurisdictions in which we operate.

Income from discontinued operations, net of tax

	Years Ended March 31,		
	2021	2020	Change
	(in thousands)		
Income from discontinued operations, net of tax	$—	$ 1,578,426	$ (1,578,426)

Income from discontinued operations, net of tax was $1,578.4 million for the year ended March 31, 2020 and consisted of a $1,985.9 million gain on sale of business resulting from the Sumitomo Transaction, partially offset by the net losses of the entities for which we transferred our entire ownership interest to Sumitomo. Refer to Note 5, “Sumitomo Transaction Agreement” of our consolidated financial statements included elsewhere in this prospectus for additional information.

Liquidity and Capital Resources

Overview

For the six months ended September 30, 2021 and 2020, we incurred net losses of $326.7 million and $61.5 million, respectively. As of September 30, 2021, we had cash and cash equivalents of approximately $2.5 billion and our accumulated deficit was approximately $2.2 billion.

For the years ended March 31, 2021 and 2020, we incurred losses from continuing operations of $900.2 million and $568.1 million, respectively. As of March 31, 2021, we had cash and cash equivalents of approximately $2.1 billion and our accumulated deficit was approximately $1.9 billion.

We have not generated any revenues to date from the sale of our product candidates. Our revenue, primarily generated through license agreements as well as from subscription and service-based fees, has not been significant to date. Our operations to date have been financed primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements.

Sources of Liquidity

Roivant Equity Financing Transactions

Since inception, we have completed multiple equity financing transactions, including the following financing transaction completed during the year ended March 31, 2020 and six months ended September 30, 2021.

In December 2019, in connection with the Sumitomo Transaction, we raised net proceeds of approximately $999.2 million in connection with the sale of our Common Shares to Sumitomo.

In September 2021, we completed our Business Combination with MAAC, a special purpose acquisition company, as well as concurrent PIPE Financing. In connection with the Business Combination and PIPE Financing, we received $213.4 million in cash at closing.

Sumitomo Transaction

In December 2019, we closed the Sumitomo Transaction, including the transfer of our ownership interest in five Vants—Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd.,

and Spirovant Sciences Ltd.—to Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo. In addition, in connection with the Sumitomo Transaction, we (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of our ownership interests in six other subsidiaries (Dermavant, Genevant, Lysovant Sciences Ltd. ("Lysovant"), Metavant Sciences Ltd. ("Metavant"), Roivant Asia Cell Therapy Holdings Ltd. ("Cytovant Parent") and Sinovant Sciences HK Limited ("Sinovant")), and (ii) (a) transferred the proprietary technology platform DrugOme to Sumitomo (for which Roivant retains a perpetual royalty free license for internal use) and (b) licensed the Digital Innovation technology platform to Sumitomo (for which both parties retain ongoing access). In exchange for these components of the Sumitomo Transaction, we received approximately $1.9 billion in cash, which was in addition to the $999.2 million from the sale of our Common Shares to Sumitomo as discussed above.

In June 2021, we completed a transaction with Sumitomo pursuant to which Sumitomo terminated its existing options to acquire our equity interests in certain of our subsidiaries.

Consolidated Vant Equity Financing Transactions

Since inception, we have completed multiple Vant equity financing transactions, including the following financing transactions completed during the years ended March 31, 2021 and 2020 and six months ended September 30, 2021:

Immunovant

During the years ended March 31, 2021 and 2020, Immunovant issued shares of common stock for an aggregate net proceeds of $384.9 million (including an aggregate of $27.5 million of shares of common stock purchased by us) in private financings, underwritten public offerings, and warrant exercises.

Additionally, in December 2019, Immunovant Sciences Ltd. ("ISL") completed a business combination with Health Sciences Acquisition Corporation ("HSAC"), a special purpose acquisition company, pursuant to which HSAC acquired 100% of the outstanding shares of ISL (the "HSAC Transaction"). Following the HSAC Transaction, ISL became a wholly owned subsidiary of HSAC, which was renamed "Immunovant, Inc." HSAC was treated as the "acquired" company for accounting purposes. Immunovant received $111.0 million in cash as a result of the HSAC Transaction, consisting of the funds held in HSAC's trust account. The proceeds included $5.1 million related to common shares purchased by us.

Proteovant

In December 2020, following Proteovant Sciences, Inc's ("Proteovant") acquisition of Oncopia in November 2020, SK, Inc. (formerly known as SK Holdings Co., Ltd.) ("SK") entered into a subscription agreement (the "SK Subscription Agreement") pursuant to which SK agreed to make a $200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date. In January 2021, in accordance with the terms of the SK Subscription Agreement, SK made the first payment of $100.0 million to Proteovant. In July 2021, Proteovant collected the subscription receivable relating to the second $100.0 million payment due under the SK Subscription Agreement.

Consolidated Vant Debt Financings

Since inception, we have completed multiple Vant debt financings, including the following debt financings completed during the year ended March 31, 2020 and six months ended September 30, 2021:

Dermavant

In May 2019, Dermavant entered into a loan and security agreement (the "Hercules Loan Agreement") with Hercules, pursuant to which Dermavant borrowed an aggregate of $20.0 million. In May 2021, all amounts

outstanding under the Hercules Loan Agreement were repaid using the proceeds from the $40.0 million senior secured credit facility entered into by Dermavant with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent in May 2021, and Dermavant terminated the Hercules Loan Agreement.

Other

Datavant

In July 2021, we received approximately $320 million in cash as a result of the Datavant Merger.

Funding Requirements

We expect to continue to incur significant and increasing operating losses at least for the foreseeable future. We do not expect to generate product revenue until we successfully complete development and obtain regulatory approval for any of our current or future product candidates, which may never occur. Our operating results, including our net losses, may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, our expenditures on other research and development activities and our pre-commercialization efforts. We anticipate that our expenses will increase substantially as we:

- fund preclinical studies and clinical trials for our product candidates, which we are pursuing or may choose to pursue in the future;
- fund the manufacturing of drug substance and drug product of our product candidates in development;
- seek to identify, acquire, develop and commercialize additional product candidates;
- invest in activities related to the discovery of novel drugs and advancement of our internal programs;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- achieve milestones under our agreements with third parties that will require us to make substantial payments to those parties;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- begin to operate as a public company.

We expect to continue to finance our cash needs through a combination of our cash on hand and future equity offerings, debt financings, sales of subsidiaries, and collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties, we may be required to relinquish valuable rights to our technologies,

future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

Cash Flows

The following table sets forth a summary of our cash flows for the six months ended September 30, 2021 and 2020:

	Six Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (261,766)	$ (209,212)
Net cash provided by (used in) investing activities	$ 315,070	$ (27,505)
Net cash provided by financing activities	$ 314,144	$ 357,086

The following table sets forth a summary of our cash flows for the years ended March 31, 2021 and 2020:

	Years Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$(552,138)	$ (758,750)
Net cash (used in) provided by investing activities	$ (31,702)	$1,694,790
Net cash provided by financing activities	$ 456,264	$ 214,081

The cash flows from discontinued operations have not been segregated and are included in the statements of cash flows for the year ended March 31, 2020. Refer to Note 6, “Discontinued Operations” of our financial statements included elsewhere in this prospectus for further information regarding our discontinued operations.

Operating Activities

Cash flow from operating activities represents the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash flow from operating activities is derived from adjusting our net loss (income) for non-cash items and changes in working capital.

For the six months ended September 30, 2021, cash used in operating activities increased by $52.6 million to $261.8 million compared to the six months ended September 30, 2020. This increase was primarily driven by an increase in cash required to fund operations, particularly as a result of the progression of Vant programs along with recent asset acquisitions.

For the year ended March 31, 2021, cash used in operating activities decreased by $206.6 million to $552.1 million compared to the year ended March 31, 2020. This decrease was primarily driven by the reduction in cash required to fund the operations of Vants sold to Sumitomo in December 2019, partially offset by an increase in upfront cash consideration for IPR&D relating to asset acquisitions and license agreements.

Investing Activities

Cash flow from investing activities includes cash used for acquisitions, net of cash acquired; proceeds from investments; dispositions, net of cash disposed; capital expenditures; and purchases of equity securities and other investments. Cash flow from investing activities also includes cash provided by sale of business.

For the six months ended September 30, 2021, cash flow from investing activities changed by $342.6 million to net cash provided by investing activities of $315.1 million from net cash used in investing activities of $27.5 million for the six months ended September 30, 2020. This change in cash flow from investing activities is primarily due to approximately $320 million in cash we received as a result of the Datavant Merger.

For the year ended March 31, 2021, cash flow from investing activities changed by $1,726.5 million to net cash used in investing activities of $31.7 million from net cash provided by investing activities of $1,694.8 million for the year ended March 31, 2020. This change in cash flow from investing activities is primarily attributed to proceeds from the sale of business, net of cash disposed, in December 2019, resulting from the Sumitomo Transaction.

Financing Activities

For the six months ended September 30, 2021, cash provided by financing activities decreased by $42.9 million to $314.1 million compared to the six months ended September 30, 2020. During the six months ended September 30, 2021, proceeds were generated by the completion of our Business Combination and PIPE financing in September 2021, payment of the subscription receivable due to Proteovant by SK in July 2021, and the senior secured credit facility entered into by Dermavant and certain of its subsidiaries with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent, partially offset by cash used to repay all amounts outstanding under a previously existing loan and security agreement with Hercules Capital, Inc. During the six months ended September 30, 2020, proceeds were generated from the issuance of equity at our majority-owned subsidiary Immunovant, Inc.

For the year ended March 31, 2021, cash provided by financing activities increased by $242.2 million to $456.3 million compared to the year ended March 31, 2020. This change was primarily driven by higher net proceeds from the issuance of subsidiary equity, resulting from the issuance of Immunovant common stock upon completing two underwritten public offerings and warrant exercises and the issuance of Proteovant common stock to SK, during the year ended March 31, 2021 as compared to net proceeds from the issuance of subsidiary equity during the year ended March 31, 2020. During the year ended March 31, 2020, proceeds were also generated from the issuance of our Common Shares and the Sumitomo Options pursuant to the Sumitomo Transaction as well as from subsidiary debt financings. However, these proceeds were largely offset by cash used to repurchase certain of our Common Shares and equity awards along with cash used to purchase subsidiary equity and repay certain subsidiary long-term debt and convertible debt during the year ended March 31, 2020.

Outlook

We expect our existing cash and cash equivalents will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next twelve months based on current operating plans and financial forecasts. However, we have based this estimate on assumptions that may prove to be wrong, which may require us to use our capital resources sooner than expected. See “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” in this prospectus.

Contractual Obligations and Commitments

We have certain payment obligations under various asset acquisition and license agreements. Under these agreements we are required to make milestone payments upon successful completion and achievement of certain development, regulatory and commercial milestones. The payment obligations under the asset acquisition and license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones, and we will be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements. The achievement and timing of these future milestone payments are not probable or reasonably estimable, and therefore such amounts have not been included on our condensed consolidated balance sheet as of September 30, 2021.

We enter into agreements in the normal course of business with CROs and other vendors for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

Our contractual obligations also include operating lease liabilities, primarily relating to real estate leases. Refer to Note 13, "Leases" of our audited financial statements included elsewhere in this prospectus for further information regarding our leases.

Loan and Security Agreement between Dermavant and Hercules

In May 2019, Dermavant entered into the Hercules Loan Agreement with Hercules as agent and lender, under which Dermavant, borrowed an aggregate of $20.0 million (the "2019 Term Loan"). The 2019 Term Loan was fully drawn in May 2019. In May 2021, Dermavant repaid all amounts outstanding under the Hercules Loan Agreement using the proceeds from the $40.0 million Credit Facility entered into by Dermavant and certain of its subsidiaries in May 2021, and Dermavant terminated the Hercules Loan Agreement. See "Dermavant Senior Secured Credit Facility" below for additional information.

Funding Agreement between Dermavant and NovaQuest

In July 2018, as a result of Dermavant's acquisition of tapinarof from GlaxoSmithKline Intellectual Property Development Ltd. and Glaxo Group Limited (collectively "GSK"), Dermavant entered into the NovaQuest Facility, pursuant to which Dermavant is required to make milestone and other quarterly interest payments to NovaQuest Co-Investment Fund VIII, L.P. ("NovaQuest") upon the achievement of certain regulatory and commercial milestones for tapinarof in either psoriasis or atopic dermatitis in the United States, the European Union and Japan. These obligations terminate upon marketing approval revocation or withdrawal of tapinarof for health and safety reasons by either (x) the U.S. Food and Drug Administration (the "FDA") or (y) Dermavant, Dermavant's affiliates, or any sublicensee. The aggregate maximum amount of regulatory milestone payments Dermavant could be required to make under the NovaQuest Facility is $440.6 million and the maximum aggregate amount of commercial milestone payments Dermavant could be required to make under the NovaQuest Facility is $141.0 million. In some circumstances, Dermavant may be able to offset certain of the regulatory milestone payments with up to $88.1 million of the commercial milestone payments. Dermavant is also required to make significant payments to NovaQuest if development of tapinarof is terminated or if Dermavant terminates development of tapinarof for one indication and receives approval for the other. NovaQuest is not obligated to refund to Dermavant any payments previously made under the NovaQuest Facility.

Dermavant Senior Secured Credit Facility

In May 2021, DSL, Dermavant Holdings Limited, Dermavant Sciences IRL Limited and DSG, as borrowers and certain other subsidiaries of DSL, as initial guarantors, entered into a $40.0 million senior secured credit facility (the "Credit Facility") with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent. The Credit Facility has a five-year maturity and bears an interest rate of 10.0% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter through the maturity date. A lump sum principal payment is due on the maturity date.

Palantir Master Subscription Agreement

In May 2021, we entered into a master subscription agreement with Palantir Technologies Inc. ("Palantir") for access to Palantir's proprietary software for a five-year period. The remaining minimum payments for this software subscription are $39.0 million.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements, as defined under SEC rules, during the periods presented.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingencies as of the dates of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Any references to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (the "ASC"), and Accounting Standards Updates ("ASU"), issued by the Financial Accounting Standards Board (the "FASB"). The consolidated financial statements include the accounts of Roivant and our subsidiaries in which we have a controlling financial interest, most often through a majority voting interest.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

While our significant accounting policies are described in more detail in Note 2, "Summary of Significant Accounting Policies" in our consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred.

We accrue expense for preclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine such estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion and the agreed-upon fee to be paid for such services. However, actual costs and timing of preclinical studies and clinical trials are highly uncertain, subject to risks, and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

We evaluate license agreements and asset acquisitions for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, we expense payments made under such license agreements as research and development expense.

Share-Based Compensation

We recognize compensation costs related to share-based awards granted to employees, directors, and consultants based on the estimated fair value of the awards on the date of grant. The grant date fair value of the stock-based awards is recognized over the requisite service period, which is generally the vesting period of the
respective awards. We may grant awards with graded-vesting features. When such awards have only service vesting requirements, we elected to record share-based compensation expense on a straight-line basis. If awards with graded-vesting features contain performance or market conditions, then we record share-based compensation expense using the accelerated attribution method.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including the fair value of our Common Shares prior to our initial public offering, volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These subjective assumptions are estimated as follows:

Fair value of common share—Prior to the closing of the Business Combination, as a privately held company, we estimated the fair value of the shares of common stock underlying our share-based awards on each grant date. To determine the fair value of our Common Shares underlying option grants, we considered, among other things, valuations of our common share prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The estimation of the fair value of the Common Shares considered factors including the following:

- the prices of our Common Shares sold to investors in arm's length transactions;
- the estimated present value of our future cash flows;
- our business, financial condition and results of operations;
- our forecasted operating performance;
- the illiquid nature of our Common Shares;
- industry information such as market size and growth;
- market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and
- macroeconomic conditions.

We apply similar methodology to estimate the fair value of the shares of common stock underlying share-based awards at our privately held Vants. Now that our Common Shares are publicly traded, we determine the fair value of each common share underlying share-based awards based on the closing price of our Common Shares as reported by the Nasdaq on the date of grant and therefore it will not be necessary to determine the fair value of the new stock-based award pursuant to the methodology described above.

Expected term—We have generally elected to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected volatility—Prior to the closing of the Business Combination, we were a privately held company and did not have any trading history for our common share; accordingly, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We apply similar methodology to estimate the expected volatility at

our privately held Vants. Because we do not have an extended trading history for our shares of common stock since the closing of the Business Combination, the method used to estimate the expected volatility remained unchanged.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options at the time of the grant.

Expected dividend yield—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options; therefore, we have estimated the dividend yield to be zero.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Summary of Significant Accounting Policies" in our consolidated financial statements included elsewhere in this prospectus.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Quantitative and Qualitative Disclosures about Market Risk

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this report.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an "emerging growth company" within the meaning of the JOBS Act. As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, certain requirements related to the disclosure of executive compensation in this prospectus and in our periodic reports and proxy statements, and the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We have also taken advantage of the ability to provide reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. However, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold shares.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the first sale of Roivant Common Shares pursuant to an effective registration statement or (b) in which we have total annual gross revenue of at least $1.07 billion (as adjusted for inflation pursuant to SEC rules from time to time), and (2) the date on which (x) we are deemed to be a large accelerated filer, which means the market value of Roivant Common Shares that are held by non-affiliates exceeds $700 million as of the prior September 30th, or (y) the date on which we have issued more than $1.0 billion in nonconvertible debt during the prior three-year period.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Common Shares held by non-affiliates exceeds $250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our Common Shares held by non-affiliates exceeds $700 million as of the end of that year’s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies more difficult.

BUSINESS

References to "Roivant," "the Company," "we," "us" or "our" in the following section refer to Roivant Sciences Ltd. and its subsidiaries, unless the context otherwise requires.

Overview

We are building the next-generation "big pharma" company, organized to harness modern technologies and the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity.

We are a diverse team of experienced drug developers, scientists, physicians, company builders, data scientists and engineers, biopharma investors, physicists and business development professionals dedicated to improving the lives of patients. At Roivant, we combine our team's extensive experience and multi-disciplinary expertise with innovative technologies to identify and advance potentially transformative medicines.

We deploy a hypothesis-driven approach to identify novel or clinically-validated targets and biological pathways in areas of high unmet medical need. We then seek to acquire, in-license or discover promising drug candidates against those targets or pathways. Our small molecule discovery engine is powered by a unique combination of leading computational physics and machine learning ("ML") capabilities for *in silico* drug design.

We develop drug candidates in subsidiary companies we call "Vants" with a distinct approach to sourcing talent, aligning incentives and deploying technology. Each of our Vant teams is built with deep relevant expertise to promote successful execution of our development strategy. Our Vants continue to benefit from the support of the Roivant platform and technologies that are built to address inefficiencies in the drug discovery, development and commercialization process.

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology, hematology and oncology, and modalities, including biologics, topicals, gene therapies and bifunctional small molecules. We currently have 14 Vants and, together, we are advancing a deep and diversified pipeline of over 30 drug candidates. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately $940 million in the Public Vants as of September 30, 2021 (inclusive of the value of the Myovant Top-Up Shares). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

- conducted nine international Phase 3 trials, the last eight of which have been successful;
- consummated a $3 billion upfront partnership with Sumitomo (see "—Platform Recognition");
- developed four drugs that received FDA approval after their transfer to Sumitomo;
- built a pipeline of over 30 drug candidates ranging from early discovery to registration;
- launched Roivant Discovery, our small molecule discovery engine, consisting of a collection of advanced computational physics capabilities, integrated with an in-house wet lab facility; and
- created innovative software tools to optimize each stage of the drug discovery, development and commercialization process.

Today, we have 14 Vants. We plan to create additional Vants based on the outputs of the Roivant platform, including our in-licensing efforts and our small molecule discovery engine, Roivant Discovery. The following table summarizes our Vants:

Vant	Roivant Ownership at September 30, 2021		Description	Lead Program / Mechanism	Modality	Indication(s) /Phase	Upcoming Milestones
	Basic	Fully Diluted					
Dermavant	100%	85%	Developing treatments for unmet needs in immuno-dermatology	Tapinarof / Therapeutic aryl hydrocarbon receptor modulating agent	Topical	• Psoriasis /Registration Atopic dermatitis / Phase 3	• Q2 ‘22: FDA approval decision on Tapinarof for psoriasis • 1H ‘23: Topline Phase 3 data in atopic dermatitis
Immunovant	64%*	59%*	Developing an anti-FcRn monoclonal antibody for IgG-mediated autoimmune diseases	Batoclimab / Anti-FcRn monoclonal antibody	Biologic	• Myasthenia gravis, thyroid eye disease, and warm autoimmune hemolytic anemia / Phase 2	• 1H ‘22: Initiate pivotal trial in MG • TBA: Reinitiate program in TED • TBA: Reinitiate program in WAIHA • 2H ‘22: Announce at least two new indications for batoclimab
Aruvant	88%	79%	Developing transformative gene therapies for severe blood disorders	ARU-1801 / Ex vivo lentiviral gene therapy delivering a novel, highly potent variant of fetal hemoglobin (HbF)	Gene therapy	• Sickle cell disease / Phase 1/2	• 2022: Additional data from ARU-1801 Phase 1/2 • 1H ‘23: ARU-1801 Phase 3 initiation
Proteovant	60%	60%	Developing heterobifunctional protein degraders for oncology, neurology, and immunology, with exclusive access to VantAI	AR Degrader	Small Molecule	• Prostate cancer / Preclinical	• 2022: AR degrader Phase 1 initiation
Lysovant	100%	99%	Developing a novel endolysin for hard-to-treat Staph aureus infection	LSVT-1701 / Endolysin	Biologic	• Staph aureus bacteremia and infective endocarditis / Phase 1	• 1H ‘22: LSVT-1701 MAD initiation
Kinevant	88%	88%	Developing an anti-GM-CSF monoclonal antibody for autoimmune diseases	Namilumab / Anti-GM-CSF monoclonal antibody	Biologic	• Sarcoidosis / Phase 1	• 1H ‘22: Namilumab Phase 2 initiation

Vant	Roivant Ownership at September 30, 2021 Basic	Roivant Ownership at September 30, 2021 Fully Diluted	Description	Lead Program /Mechanism	Modality	Indication(s) /Phase	Upcoming Milestones
Affivant	100%	99%	Developing bispecific antibodies for oncology indications with unmet medical need	AFM32 / Bispecific antibody	Biologic	• Solid Tumors / Preclinical	• 1H '23: File IND
Cytovant	72%	68%	Developing cellular medicines uniquely suited to Asian patients	CVT-TCR-01 / TCR-T targeting NY-ESO-1	Cell therapy	• Oncologic malignancies / Preclinical	
Arbutus	29%*	27%*	Developing a potential cure for chronic HBV infection	AB-729 / RNAi inhibiting HBV replication	RNA therapy	• Hepatitis B / Phase 2	• 2022: Initial data from Phase 2 AB-729 combination trial with vebicorvir • Early 2022: Initiate Phase 2a AB-729 combination trial with VTP-300 • 2022: Additional data from Phase 1a/b AB-836 trial
Sio Gene Therapies	25%*	24%*	Developing gene therapies for neurodegenerative diseases	AXO-AAV-GM1 / In vivo AAV9 gene therapy	Gene therapy	• GM1 gangliosidosis / Phase 1/2	• 1H '22: Data update from ongoing Phase 1/2 trial
Genevant	83%	67%	Advancing delivery of nucleic acid therapeutics	—	—	—	—
Lokavant	90%	84%	Optimizing trial operations with an end-to-end risk monitoring solution	—	—	—	—
Datavant	**	**	Connecting patient-level health data through privacy-first, HIPAA-compliant tokens	—	—	—	—
Alyvant	97%	95%	Leveraging data and artificial intelligence to connect patients to therapies	—	—	—	—

Note: Excludes early-stage pipeline of protein degraders and inhibitors being developed through our small molecule discovery engine. All drugs in current pipeline are investigational and subject to health authority approval. Where applicable, upcoming milestones are contingent on FDA feedback.

Ownership figures as of September 30, 2021. Arbutus basic and fully diluted ownership includes the conversion of preferred shares held by Roivant into Common Shares, which was completed on October 18, 2021. Roivant ownership in Cytovant includes both direct and indirect ownership.

* Denotes entities that are publicly traded.

** In June 2021, Datavant entered into a definitive merger agreement to combine with Ciox Health. The transaction closed on July 27, 2021. The implied enterprise value of the combined company at the conversion price cap of the new preferred equity investment made concurrently with the closing of the merger was $7.0 billion. This enterprise value implies an equity value of $6.1 billion (after netting out approximately $900 million of debt and other adjustments). No assurance can be given that the implied enterprise or equity value is an accurate reflection of the value of the combined business at closing or in the future. At closing of the merger and assuming a $7.0 billion enterprise value, Roivant's ongoing, fully diluted equity ownership in the combined entity was approximately 12% (without giving effect to certain liquidation preferences held by the preferred equity shareholders).

The following table summarizes our development-stage product candidate pipeline.

Development Pipeline

Product Candidate	Indication	Vant	Modality	Phase
Tapinarof	Psoriasis	Dermavant	Topical	Registration
Tapinarof	Atopic Dermatitis	Dermavant	Topical	Phase 3
Cerdulatinib	Vitiligo	Dermavant	Topical	Phase 2
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 2
Batoclimab	Warm Autoimmune Hemolytic Anemia	Immunovant	Biologic	Phase 2
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 2
ARU-1801	Sickle Cell Disease	Aruvant	Gene Therapy	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 1
LSVT-1701	Staph Aureus Bacteremia	Lysovant	Biologic	Phase 1
Cerdulatinib	Atopic Dermatitis	Dermavant	Topical	Phase 1
DMVT-504	Hyperhidrosis	Dermavant	Small Molecule	Phase 1
DMVT-503	Acne	Dermavant	Topical	Preclinical
ARU-2801	Hypophosphatasia	Aruvant	Gene Therapy	Preclinical
AFM32	Solid Tumors	Affivant	Biologic	Preclinical
CVT-TCR-01	Oncologic Malignancies	Cytovant	Cell Therapy	Preclinical

Note: All drugs in current pipeline are investigational and subject to health authority approval.

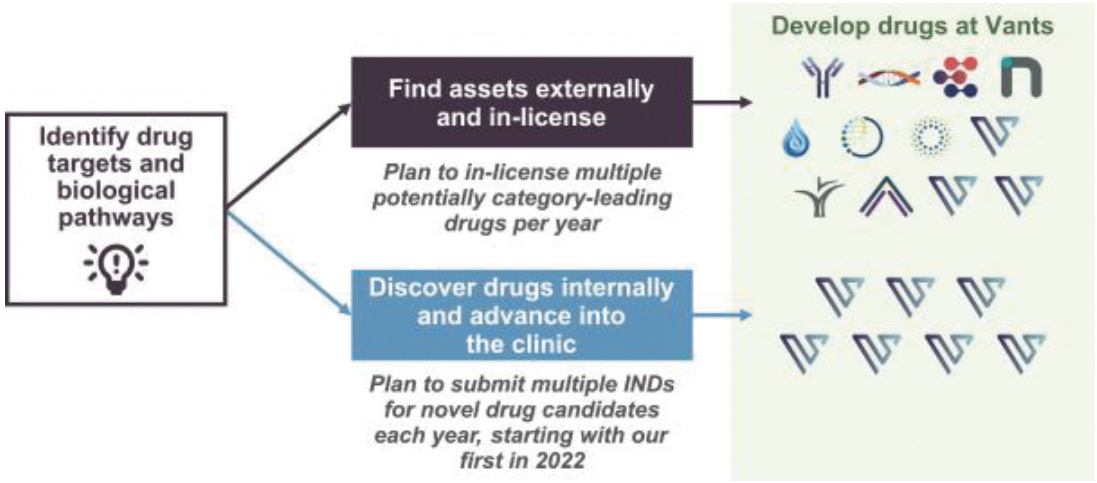
As part of our mission to redefine "big pharma," we aim to develop transformative medicines faster for diseases for which there are no approved therapies or the current standard of care treatment has significant limitations or drawbacks. We believe we are uniquely positioned to accomplish this by:

- Relentlessly pursuing opportunities to in-license or acquire drugs that we believe can deliver successful outcomes on accelerated timelines;
- Designing creative deal structures to balance risk and the potential for future value creation;
- Using our computational drug discovery technologies to design and identify compounds with the greatest probability of success early in the discovery process;
- Creating nimble, entrepreneurial Vants that operate similar to independent biotechnology companies where each management team, comprised of world-class drug developers and clinical operators, is solely focused on their respective Vant's mission;
- Incentivizing employees with equity in their Vants, which encourages focus and calculated risk-taking;
- Providing operational support from our centralized functions to accelerate Vant formation and operational maturation;

- Developing proprietary computational technologies that leverage our unique position at the intersection of biopharma and technology;
- Providing Vants with access to our team of scientific experts, physicians and technologists to help optimize their clinical development and commercial strategies; and
- Leveraging our business development engine and vast network of industry relationships for the identification of value-creating collaborations and synergistic partnerships.

Through continued investment in our model, we believe we are well-positioned to advance our current pipeline through regulatory approval and commercialization, expand our pipeline through novel drug discovery and in-licensing and acquisition transactions, and execute on our vision of transforming the delivery of healthcare to patients.

Our Process



Discover

We focus on developing potentially transformative medicines that address areas of significant unmet medical need. We take a hypothesis-driven approach, focusing on compelling pathways, targets and drug classes that we believe lack established leaders, and we proactively pursue or discover drugs that align with our hypotheses. We focus on building diversification and varied risk profiles into our pipeline and are agnostic to therapeutic area, stage of development and drug modality. We leverage internally developed technologies as well as a multi-disciplinary team with diverse backgrounds to evaluate the universe of targets and biological pathways that we deem compelling. Once we have built conviction around a specific target or biological pathway, we look for assets to in-license or acquire, and/or design novel drugs through our small molecule discovery engine.

Our ability to rapidly identify and execute in-licensing opportunities is underpinned by our diverse business development team, which consists of former investment professionals and experienced R&D and data scientists. A suite of tools that we built in-house supports our business development team by bringing a computationally driven approach to the identification of in-licensing opportunities as well as supporting our R&D decision-making across all stages of the drug discovery and development process. Our track record in R&D and our ability to implement creative deal structures ensures that we are a favored development partner and are able to acquire assets on attractive terms with shared risk and aligned incentives. We have been successful in-licensing drugs from global pharmaceutical companies, small biotech startups and academic centers around the world, and we

are proud of our deep network of academic and industry partners. Our goal is to add multiple potentially category-creating or category-leading drugs to our pipeline each year through this in-licensing strategy, a pace which is consistent with our track record over the past several years.

As a complement to our in-licensing strategy, we also apply our hypothesis-driven approach to our small molecule discovery engine, ensuring we direct our efforts toward high value pathways, targets and drug classes. Our discovery engine is defined by the distinctive combination of capabilities in computational physics and ML. Through the acquisition of Silicon Therapeutics, we have world-leading capabilities in computational physics for drug design. Silicon Therapeutics has built an advanced computational physics platform integrated with a proprietary supercomputing cluster and a wet-lab facility equipped for generating a broad range of experimental data. We have also built a ML platform, VantAI, tailored to the *in silico* design and optimization of novel protein degraders in development at Proteovant. We believe the unique combination of both computational physics and ML capabilities will position us as the leader in computational drug discovery and establish a sustainable source of future small molecule drug candidates.

Our discovery engine has broad capabilities across multiple categories of small molecules and an initial special focus on targeted protein degradation, a therapeutic approach with broad potential applicability to diseases associated with protein overactivity and with no incumbent leader. Our capabilities in targeted protein degradation include a long-term partnership with a leading academic lab, the ability to optimize our degraders using both computational physics and ML and our well-established clinical development capabilities. Based on promising early-stage preclinical data for our first computationally-designed degrader candidates, we believe that our computational approach can generate candidates that achieve real-world degradation against relevant targets.

We anticipate that our discovery engine will expand our clinical-stage pipeline by generating candidates to advance through the launch of potential new Vants, or to integrate with existing Vants if there is appropriate therapeutic area overlap, in either case taking advantage of Roivant's established clinical development capabilities.

Develop

We believe the Vant model accelerates successful execution due to three key factors: nimble teams, incentive alignment and robust governance. We build Vant teams with deep, relevant expertise to promote successful execution of development strategy. By keeping Vant teams focused and generally small, we strive to eliminate excessive bureaucracy, thereby facilitating rapid decision-making and ultimately accelerating outcomes. Vants are built as entrepreneurial biotech companies, where each Vant leader is compensated with significant upside potential in the form of Vant equity. By aligning employee incentives with successful Vant outcomes, we encourage Vant leaders to take calculated risks and implement strategies that we believe differentiate the speed and creativity of development capabilities from legacy large pharmaceutical companies, where drug developers may face asymmetric downside in the event of failure and where upside equity, if granted, is diluted by many diverse projects. Vants are also supported through a robust governance structure that is centralized at Roivant. Our governance team ensures accountability for execution at Vants and allows us to capture synergies through shared technology and certain future shared commercial functions, while at the same time providing access to a broad range of Roivant resources when Vants face critical strategic questions.

Commercialize or monetize

The Vant model is designed to maximize the value of each drug that we successfully develop and generate returns for shareholders through the independent commercialization of products, partnerships with pharmaceutical and biotechnology companies or the selective sale of Vants. Our primary objective is to launch commercial products ourselves, but we may sell or partner Vants or specific drugs based on the facts and circumstances, including, without limitation, the strategic rationale and financial return potential.

Our Technologies

Our platform leverages technologies that are designed to optimize each stage of the drug discovery, development and commercialization process.

Our small molecule discovery engine at Roivant Discovery powers *in silico* drug discovery through the combination of two distinct approaches to computational drug design: the physics approach and the ML approach. The physics approach applies quantum mechanics and statistical thermodynamics to model the behavior of and interactions between molecules in a biological system. This includes molecular dynamics simulations, which predict how potential drug molecules bind to and modulate therapeutic protein targets. ML approaches for drug design, meanwhile, use pattern-recognition algorithms to discern mathematical relationships from empirical observations of small molecules and extrapolate to predict chemical, biological and physical properties of novel compounds. ML techniques are very efficient in terms of computing power consumed compared to physics-based approaches and can be scaled to large datasets without the need for extensive computational resources. To effectively build a leadership position in computational drug discovery, we deliberately built and assembled capabilities in both computational physics and ML, creating a combined platform that we believe to be significantly differentiated from others.

The key components of our small molecule discovery engine include:

- ***A quantum mechanics-based molecular dynamics software platform to predict the interactions, energies and conformational behavior of targets and generate novel drug candidates.*** We can simulate hundreds of molecules per day and make predictions for drug design, enabling the optimization of properties such as binding affinity, selectivity, membrane permeability and solubility. We also have a suite of molecular dynamics and simulation tools to generate additional insights regarding individual atomic contributions to binding properties and conformational dynamics.
- ***A supercomputing cluster composed of over 600 graphics processing units***. Our supercomputing cluster allows us to run molecular simulations at biologically meaningful timescales predicting not only affinity but also how biomolecules will respond at an atomic level to perturbations such as mutation, phosphorylation, protonation, or the addition or removal of a ligand and functionally important structural changes in proteins.
- ***A suite of degrader-specific ML tools.*** We have developed a novel protein contact-first workflow that utilizes information about known protein-protein interactions to build new degraders that can effectively stabilize target-E3 interfaces; a degron knowledge graph, which we believe to be industry-leading, to map the ubiquitin proteasome system; and a unique model, based on millions of carefully curated protein stability datapoints, to predict degradation.
- ***A wet lab fully equipped for synthetic chemistry, crystallography, biophysics, biochemistry and biology*.** Our in-house laboratories are tightly integrated with our computational physics platform to directly augment simulations with biophysical data as well as validate simulation predictions. Certain experimental techniques enable more accurate and efficient simulations on targets where we lack crystal structures. Combined with homology modeling and X-ray crystallography, this allows for the simultaneous design of chemical matter against a target while refining atomistic structural models and solving high-resolution crystal structures.

Our computational physics capabilities, which we obtained through the acquisition of Silicon Therapeutics, allow us to predict how molecules will interact by using principles of quantum physics to computationally model the forces and energies of the atomic and sub-atomic particles that comprise the molecule system. Based on internal and published benchmarks, we believe that the speed and accuracy of binding free energy calculations made by our programs are on par with the best commercially available tool, Schrödinger's FEP+, and superior to open-source methods. Further, we believe our ability to rapidly validate and constrain simulations with experimental data generated in-house creates a sustainable advantage compared to competitors. These

capabilities power *in silico* assays that allow us to potentially predict binding affinity of a ligand and protein, predict conformational dynamics of a protein as it shifts from active to inactive state, and identify binding sites on a protein.

VantAI combines cutting-edge ML techniques with deep systems biology expertise to power the discovery of novel protein degraders. VantAI's distinctive degrader platform includes a novel "protein contact-first" workflow that uses graph representations of known protein-protein interactions to design new degraders that can effectively stabilize target-E3 interfaces; an industry-leading ubiquitin proteasome system map allowing for the identification of degron motifs; and complex models for protein degradation and prediction of key chemical properties, trained on over five years of proprietary degrader-specific experimental data and millions of carefully curated protein stability datapoints. Our VantAI-designed degrader candidates have produced promising early-stage preclinical data that suggests our computational approach can generate candidates that achieve real-world degradation against multiple relevant targets. The use of VantAI's computational technology on compounds for the inducement of protein degradation will be dedicated exclusively to Proteovant until at least early 2026, other than certain pre-specified work on designated targets being conducted for third parties.

We believe that our small molecule discovery engine may allow us to replace experimental assays with *in silico* assays, resulting in decreased time and costs, ultimately accelerating the hit-to-lead and lead optimization stages of the drug discovery process. Further, we expect to increase our likelihood of identifying novel binding pockets on previously "undruggable" targets. We plan to direct our expanding capabilities in computational drug discovery towards targets selected with the same "investment lens" we use for our in-licensing strategy, and we expect it to produce candidates for continued clinical development within our existing clinical trial infrastructure.

The hypothesis generation for both our internal discovery engine and in-licensing strategies is supported by a tool we developed in-house called DrugOme, which we sold as part of the Sumitomo Transaction but retain a perpetual license to. DrugOme is a comprehensive map of targets and drug candidates in development that enables differentiated analysis of development strategies and potential business development opportunities. DrugOme employs natural language processing to extract, ingest and harmonize data across diverse structured and unstructured sources to construct a centralized database that captures available data regarding clinical trials, company financials, prescriptions and intellectual property. This database informs R&D decision-making across all stages of the drug discovery and development process. DrugOme supports our business development by rapidly defining the competitive and therapeutic landscape for a specific asset, predicting clinical trial costs, identifying trends in treatment patterns, optimizing clinical trial site and investigator selection and providing other customized analyses. We believe our computational approach to identifying assets for in-licensing and the creative drug development strategies that accompany those assets are key advantages unique to the Roivant platform.

As we have developed drugs in clinical trials, we have built technologies to improve the process of running such trials. We have aggregated many of these at our subsidiary Lokavant. Lokavant's software integrates real-time data from ongoing clinical trials and monitors risks related to time, cost and quality. Its proprietary data model serves as a "common language" for trial operational data and ensures that all trial data sources are ingested, harmonized and aggregated into a central database, allowing the trial sponsor to access operational trial data in near-real time. This approach is a substantial departure from traditional operations which typically share different types of trial data asynchronously and on multi-week delays. Algorithms trained on a proprietary dataset of operational metadata from over 1,300 trials are designed to identify the most important risks with sufficient time to empower researchers to implement interventions to mitigate those risks and deliver trial results on budget and on time. In addition to being deployed in Roivant trials, Parexel, a leading global contract research organization ("CRO"), is using Lokavant's software as its remote monitoring platform, and we intend to grow Lokavant's customer base with other CROs and trial sponsors.

In designing development and commercialization strategies for our pipeline of drugs, we also identified significant shortcomings with commercially available patient data. Today, healthcare data is siloed across

multiple fragmented data sources, limiting the ability to generate a comprehensive understanding of patient health. Datavant, a company which we founded and in which we maintain a non-controlling interest, is working to address this problem. Datavant recently merged with Ciox Health, LLC (as described below). The combined company seeks to power every exchange of health data, unlocking a massive ecosystem of companies using linked, longitudinal data to improve patient outcomes. Datavant linking technology enables the advanced use of real-world evidence, patient finding, outcomes research, and commercial analytics. Datavant's customers and partners include Janssen/J&J and other top 20 pharmaceutical companies, ZS, Medidata, Cigna, Parexel, Symphony Health, Komodo Health and the NIH. We can also use Datavant's technology to better understand the real-world health outcomes of subjects who participate in our trials beyond the duration of the trials themselves.

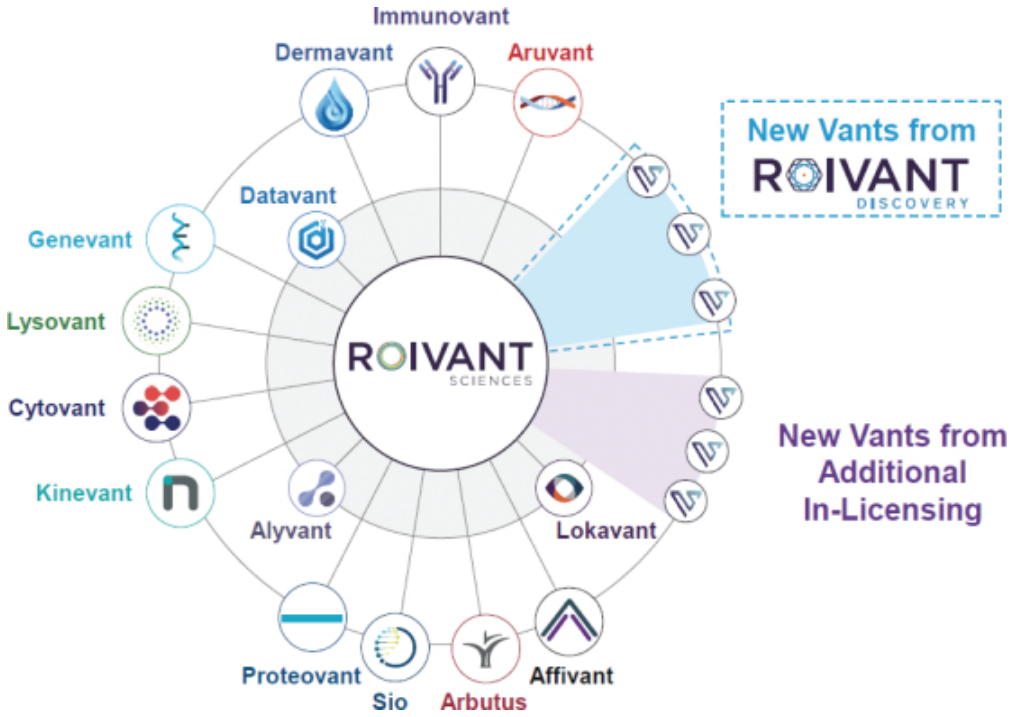
In June 2021, Datavant entered into a definitive merger agreement with CIOX Health, LLC. ("Ciox Health"), a leader in clinical data exchange. The combined entity, named Datavant, is the nation's largest health data ecosystem, enabling patients, providers, payers, health data analytics companies, patient-facing applications, government agencies, and life science companies to securely exchange their patient-level data. The merger closed in July 2021. At closing, Roivant received approximately $320 million in cash and a minority equity ownership interest in the combined entity.

We have begun to build technology to support our transition from a development-stage biopharmaceutical company into a commercial one. Alyvant is an early-stage technology product for physician and patient segmentation, targeting and engagement. Alyvant generates dynamic call plans uniquely prioritized on likelihood to prescribe by integrating patient and payor data with physician behavioral characteristics and presents those call plans through a salesforce app that drives adherence to call plans and reprioritizes physician outreach based on feedback from the field. In a 2019 pilot co-promotion of three products, Alyvant increased total prescriptions by 223% compared to the same period in the prior year and generated a >2x increase in the number of activated prescribers. As we deliver products to market, we expect to expand the suite of technology tools available to accelerate and optimize commercialization.

We will continue to execute against our goal of building the next-generation pharmaceutical company by fully integrating modern technologies at each stage of the drug discovery, development and commercialization process. We believe that there is significant opportunity to address inefficiencies within these processes, and we expect to build technologies where we find commercially available tools nonexistent or insufficient for our needs.

Unique Features of the Roivant Platform

Our model allows each Vant to rapidly scale given full access to shared technologies that address inefficiencies in the drug discovery, development and commercialization process.



Note: All trademarks are property of their respective owners.

We aim to redefine “big pharma” by rapidly developing and commercializing transformative medicines in areas of high unmet medical need where there are no approved therapies or there are significant limitations associated with current standards of care. We believe our platform is uniquely positioned to accomplish this by:

- ***Leveraging complementary approaches to identify or discover promising drug candidates:*** We assembled our current late-stage product candidate pipeline by relentlessly pursuing opportunities to in-license or acquire programs where we believe we can deliver successful outcomes on accelerated timelines. In addition, our computational drug discovery engine allows us to design, optimize and validate our own novel product candidates, providing us with another avenue to pursue compelling targets or pathways and further expand our pipeline.
- ***Creating nimble, entrepreneurial Vants****:* Vants generally operate similar to independent biotechnology companies where each management team is focused on their respective mission and are economically incentivized to maximize value through Vant-specific equity grants. Each of our Vant teams is built with deep relevant expertise to ensure successful execution of their specific development strategy. The Vant model is designed to facilitate rapid decision making and calculated risk taking, by empowering, aligning and incentivizing Vant teams around the specific outcomes of their product candidates.
- ***Developing and deploying proprietary technologies:*** We believe we are able to develop transformative medicines faster by building and applying computational tools to drug discovery, development and commercialization. We occupy a unique position at the intersection of biopharma and technology, having built our capabilities in parallel, optimizing each for synergy with the other, in contrast to big pharma who have added software tools to legacy workflows or technology startups that lack experience developing drugs. Vants have access to, and are supported by, these technologies.
- ***Allocating capital to maximize R&D efficiency:*** We apply an objective, rigorous decision framework across the drug development process designed to ensure resources and capital are continuously directed

towards programs we believe have a higher probability of success and away from those that fail to meet our internal hurdles. We centralize capital allocation decisions at the Roivant level, while distributing operational decisions to the Vants, allowing us to strategically deploy capital in high growth areas, regardless of potentially competing operational priorities.

- ***Maintaining a diversified pipeline with various risk profiles:*** We have built a pipeline of over 30 drugs across different therapeutic areas, phases of development, modalities and geographies. This approach limits our exposure to several concentrated scientific and biological risks and allows us to pursue multiple innovative hypotheses across our portfolio as we seek to develop therapies for patient populations with high unmet need.
- ***Designing creative "win-win" deal structures:*** We structure our partnerships to balance risk and the potential for future value creation. We ensure that a significant proportion of near-term expenses go toward development, allowing us to stage our investment and align incentives as well as limit losses in the event of a setback. Our scale and track record of developing product candidates assures partners that we are uniquely capable of maximizing value for patients and investors.
- ***Providing operating leverage through centralized support functions:*** Our model allows us to accelerate Vant formation and maturation by centralizing and sharing certain support functions across various Vants. Vants also benefit from access to our vast network of scientific experts, physicians and technologists to help optimize their clinical development and plans for commercialization.

Platform Recognition

In December 2019, we entered into a $3 billion upfront partnership with Sumitomo. There were four key components of this transaction:

- Sumitomo acquired 100% of Roivant's ownership interest in five Vants: Urovant, Myovant, Enzyvant, Altavant and Spirovant.
- Sumitomo acquired options to purchase Roivant's ownership interest in six additional Vants (the "Option Vants"), in each case at a purchase price calculated by reference to a specified multiple. In June 2021, Sumitomo and Roivant completed a transaction which included the termination of Sumitomo's outstanding options to acquire Roivant's ownership interest in the Option Vants. See the section titled "Recent Events—Option Vants Transaction" for additional information.
- Roivant and Sumitomo agreed to share access to two technology platforms: DrugOme and Digital Innovation, an approach to integrating technologists into business operations.
- Sumitomo acquired 26,952,143 Roivant Common Shares at a per share price of $37.10 (or 78,867,360 shares of Roivant acquired at a per share price of $12.68 after giving effect to the share subdivision completed in connection with the Business Combination).

Our Growth Strategies

We believe we are on our way to building the next generation "big pharma" company by leveraging our unique platform to transform the delivery of healthcare to patients. To support this goal and mission, we are executing on 5 key pillars of growth:

- ***Deliver successes across our current pipeline:*** Our current pipeline is comprised of multiple potentially transformative drug candidates across all stages of development, modalities and therapeutic areas. Our ability to successfully develop promising drug candidates has been evidenced through four FDA approvals from Vants sold to Sumitomo. We will continue to advance our diverse pipeline through to late-stage development and ultimately, if successful, regulatory approval, expanding our track record of pipeline successes to date.

We have a robust calendar of potential near-term catalysts, including the items set forth below. In addition, we plan to in-license multiple potentially category-leading drugs per year.

Vant	Catalyst	Expected Timing
Dermavant	Tapinarof NDA filing in psoriasis	2H 2021 ✓
	Tapinarof Phase 3 initiation in atopic dermatitis	Mid-2021 ✓
	FDA approval decision on tapinarof for psoriasis	2Q 2022
	Topline data from tapinarof Phase 3 trials in atopic dermatitis	1H 2023
Immunovant	Initiate pivotal trial in MG	1H 2022
	Reinitiate program in TED	TBA
	Reinitiate program in WAIHA	TBA
	Announce at least two new indications for batoclimab	2H 2022
Aruvant	First patient dosed with updated ARU-1801 manufacturing process	2H 2021 ✓
	Additional clinical data from ARU-1801 Phase 1/2	2H 2021 ✓
	ARU-1801 Phase 3 initiation	1H 2023
Kinevant	Namilumab Phase 2 initiation in sarcoidosis	1H 2022
Lysovant	LSVT-1701 MAD initiation	1H 2022
Proteovant	Phase 1 initiation for first degrader candidate	2022
Roivant / Proteovant	Multiple additional degrader candidates entering IND-enabling studies each year	Starting 2022

Note: References are to calendar years. All catalyst timings are based on current expectations and, where applicable, contingent on FDA feedback, and may be subject to change.

- ***Expand our pipeline through acquisitions or in-licensing transactions:*** We intend to continue to expand our existing pipeline through acquiring or in-licensing additional transformative drug candidates. Our goal is to add multiple potentially category-creating or category-leading drugs to our pipeline each year on average via this in-licensing strategy, a pace which is consistent with our track record over the past several years. We will continue to manage our pipeline like a portfolio and build diversified risk profiles across therapeutic area, target, modality and stage of development.
- ***Expand our pipeline through drug discovery:*** In parallel with our in-licensing strategy, we intend to expand our pipeline through computational discovery of novel drug candidates. Thus far, we have focused our discovery efforts towards novel protein degraders. We plan to initiate a Phase 1 trial for our first degrader candidate in 2022 and rapidly build upon our early pipeline of degraders. We expect that the significant investments we have made in our small molecule discovery engine will allow us to generate novel drug candidates internally and initiate multiple IND-enabling studies each year starting in 2022.
- ***Power our entire platform by technology:*** We have built leading capabilities in computational drug discovery with our distinctive combination of ML and computational physics platforms. Our investment in computational discovery bolsters our existing technology platform that seeks to address inefficiencies across each stage of the drug discovery, development and commercialization process. We expect to continue to make strategic investments in technology to power the entire Roivant platform, ultimately accelerating the delivery of transformative medicines to patients.
- ***Commercialize medicines independently where optimal:*** While the Roivant platform ensures flexibility on our path to value creation from each asset, we believe independently commercializing our drug candidates will unlock maximal value over the long run. Our plan for building commercial capabilities will be informed by the identification of specific, targeted opportunities to create additional value across Vants. We are presently evaluating which commercial functions to potentially build in-house and centralize across the Vants. Based on our current pipeline, we expect to market our first drug, tapinarof, in 2022.

Our Management Team

We are led by a management team of leaders with diverse backgrounds, bringing together an expansive set of capabilities across healthcare investing, clinical development, technology, medicine, venture capital, operations, finance and data science. We believe we are well-positioned to redefine what it means to be a large pharmaceutical company today based on our ability to leverage experience from within and beyond the world of pharmaceuticals.

Our management team is led by our Chief Executive Officer, Matthew Gline, with strategic guidance from our Founder and Executive Chairman, Vivek Ramaswamy. Our Chief Operating Officer, Eric Venker, M.D., Pharm.D., oversees the operations of the Roivant platform and provides oversight to our Vants as a board member. Our Chief Investment Officer, Mayukh Sukhatme, M.D., is responsible for generating hypotheses for potential new drugs, ultimately guiding target selection for our small molecule discovery engine and overseeing the evaluation of new assets to bring into our pipeline through our in-licensing strategy. Our Chief Financial Officer, Richard Pulik, manages our financial strategy and operations. Our Chief Computational Scientist, Woody Sherman, Ph.D., manages our computational physics platform. Our Vant Chair, Frank Torti, M.D., serves as chair of the board for certain of our Vants and, in that capacity, is responsible for ensuring successful execution of Vant strategy. We created the role of Vant Chair to establish clear accountability for our Vant CEOs, ensuring each Vant maintains the freedom to deploy their relevant expertise while maintaining connectivity to the Roivant platform.

We build impressive teams across all levels of the organization. We hire and develop world-class talent from diverse backgrounds in biopharma, academia, technology and finance to ensure we have all of the capabilities to design and deliver creative solutions.

Our team is united by our core values:

- ***Our singular goal is creating value for patients.*** If we deliver value for patients, value for shareholders will follow.
- ***We challenge convention.*** We believe that we can't solve problems where others have failed unless we are prepared to seek solutions others have missed.
- ***We climb the wall (or break it down, or go around it).*** "Issue spotting" isn't as valuable as "issue solving."
- ***We are insatiably curious and we sweat the details.*** We obsess over data. We seek deep understanding, not superficial familiarity.
- ***We are flexible and embrace change.*** We operate in a dynamic environment, and we thrive in ambiguity.
- ***We act with integrity.*** Our patients, our shareholders, our partners and our peers and colleagues rely on us to follow our morals, to follow the law and to protect patients and improve their lives.
- ***We are impatient.*** Patients can't wait so neither can we. We act with urgency, because we know every minute matters.
- ***Even when we work as many teams, we are one team.*** We rely on our peers to empower us, and we empower our peers in turn. We trust and believe in the excellence and best intentions of our colleagues.
- ***We believe the very biggest problems in human health are within our reach.*** We don't believe in limiting ourselves to low hanging fruit — we believe that with new computational tools, innovative approaches, and the right team we can solve any problem.

Our Vants and Pipeline

Today, we have 14 Vants. We plan to create additional Vants based on the outputs of the Roivant platform, including our in-licensing efforts and our small molecule discovery engine, Roivant Discovery. The following table summarizes our Vants.

Vant	Roivant Ownership at September 30, 2021 Basic	Roivant Ownership at September 30, 2021 Fully Diluted	Description	Lead Program / Mechanism	Modality	Indication(s) / Phase	Upcoming Milestones
Dermavant	100%	85%	Developing treatments for unmet needs in immuno-dermatology	Tapinarof / Therapeutic aryl hydrocarbon receptor modulating agent	Topical	• Psoriasis /Registration • Atopic dermatitis / Phase 3	• Q2 ‘22: FDA approval decision on Tapinarof for psoriasis • 1H ‘23: Topline Phase 3 data in atopic dermatitis
Immunovant	64%*	59%*	Developing an anti-FcRn monoclonal antibody for IgG-mediated autoimmune diseases	Batoclimab / Anti-FcRn monoclonal antibody	Biologic	• Myasthenia gravis, thyroid eye disease, and warm autoimmune hemolytic anemia / Phase 2	• 1H ‘22: Initiate pivotal trial in MG • TBA: Reinitiate program in TED • TBA: Reinitiate program in WAIHA • 2H ‘22: Announce at least two new indications for batoclimab
Aruvant	88%	79%	Developing transformative gene therapies for severe blood disorders	ARU-1801 / Ex vivo lentiviral gene therapy delivering a novel, highly potent variant of fetal hemoglobin (HbF)	Gene therapy	• Sickle cell disease / Phase 1/2	• 2022: Additional data from ARU-1801 Phase 1/2 • 1H ‘23: ARU-1801 Phase 3 initiation
Proteovant	60%	60%	Developing heterobifunctional protein degraders for oncology, neurology, and immunology, with	AR Degrader	Small Molecule	• Prostate cancer / Preclinical	• 2022: AR degrader Phase 1 initiation

Vant	Roivant Ownership at September 30, 2021 Basic	Roivant Ownership at September 30, 2021 Fully Diluted	Description	Lead Program / Mechanism	Modality	Indication(s) / Phase	Upcoming Milestones
			exclusive access to VantAI				
Lysovant	100%	99%	Developing a novel endolysin for hard-to-treat Staph aureus infection	LSVT-1701 / Endolysin	Biologic	• Staph aureus bacteremia and infective endocarditis / Phase 1	• 1H ‘22: LSVT-1701 MAD initiation
Kinevant	88%	88%	Developing an anti-GM-CSF monoclonal antibody for autoimmune diseases	Namilumab / Anti-GM-CSF monoclonal antibody	Biologic	• Sarcoidosis / Phase 1	• 1H ‘22: Namilumab Phase 2 initiation
Affivant	100%	99%	Developing bispecific antibodies for oncology indications with unmet medical need	AFM32 / Bispecific antibody	Biologic	• Solid Tumors / Preclinical	• 1H ‘23: File IND
Cytovant	72%	68%	Developing cellular medicines uniquely suited to Asian patients	CVT-TCR-01 / TCR-T targeting NY-ESO-1	Cell therapy	• Oncologic malignancies / Preclinical	
Arbutus	29%*	27%*	Developing a potential cure for chronic HBV infection	AB-729 / RNAi inhibiting HBV replication	RNA therapy	• Hepatitis B / Phase 2	• 2022: Initial data from Phase 2 AB-729 combination trial with vebicorvir • Early 2022: Initiate Phase 2a AB-729 combination trial with VTP-300 • 2022: Additional data from Phase 1a/b AB-836 trial
Sio Gene Therapies	25%*	24%*	Developing gene therapies for	AXO-AAV-GM1 / In vivo AAV9 gene therapy	Gene therapy	• GM1 gangliosidosis / Phase 1/2	• 1H ‘22: Data update from ongoing Phase 1/2 trial

Vant	Roivant Ownership at September 30, 2021 Basic	Roivant Ownership at September 30, 2021 Fully Diluted	Description	Lead Program / Mechanism	Modality	Indication(s) / Phase	Upcoming Milestones
			neurodegenerative diseases				
Genevant	83%	67%	Advancing delivery of nucleic acid therapeutics	—	—	—	—
Lokavant	90%	84%	Optimizing trial operations with an end-to-end risk monitoring solution	—	—	—	—
Datavant	**	**	Connecting patient-level health data through privacy-first, HIPAA-compliant tokens	—	—	—	—
Alyvant	97%	95%	Leveraging data and artificial intelligence to connect patients to therapies	—	—	—	—

Note: Excludes early-stage pipeline of protein degraders and inhibitors being developed through our small molecule discovery engine. All drugs in current pipeline are investigational and subject to health authority approval. Where applicable, upcoming milestones are contingent on FDA feedback.

Ownership figures as of September 30, 2021. Arbutus basic and fully diluted ownership includes the conversion of preferred shares held by Roivant into Common Shares, which was completed on October 18, 2021. Roivant ownership in Cytovant includes both direct and indirect ownership.

* Denotes entities that are publicly traded.

** In June 2021, Datavant entered into a definitive merger agreement to combine with Ciox Health. The transaction closed on July 27, 2021. The implied enterprise value of the combined company at the conversion price cap of the new preferred equity investment made concurrently closing of the merger was $7.0 billion. This enterprise value implies an equity value of $6.1 billion (after netting out approximately $900 million of debt and other adjustments). No assurance can be given that the implied enterprise or equity value is an accurate reflection of the value of the combined business at closing or in the future. At closing of the merger and assuming a $7.0 billion enterprise value, Roivant's ongoing, fully diluted equity ownership in the combined entity was approximately 12% (without giving effect to certain liquidation preferences held by the preferred equity shareholders).

The following table summarizes our development-stage product candidate pipeline:

Product Candidate	Indication	Vant	Modality	Phase
Tapinarof	Psoriasis	Dermavant	Topical	Registration
Tapinarof	Atopic Dermatitis	Dermavant	Topical	Phase 3
Cerdulatinib	Vitiligo	Dermavant	Topical	Phase 2
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 2
Batoclimab	Warm Autoimmune Hemolytic Anemia	Immunovant	Biologic	Phase 2
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 2
ARU-1801	Sickle Cell Disease	Aruvant	Gene Therapy	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 1
LSVT-1701	Staph Aureus Bacteremia	Lysovant	Biologic	Phase 1
Cerdulatinib	Atopic Dermatitis	Dermavant	Topical	Phase 1
DMVT-504	Hyperhidrosis	Dermavant	Small Molecule	Phase 1
DMVT-503	Acne	Dermavant	Topical	Preclinical
ARU-2801	Hypophosphatasia	Aruvant	Gene Therapy	Preclinical
AFM32	Solid Tumors	Affivant	Biologic	Preclinical
CVT-TCR-01	Oncologic Malignancies	Cytovant	Cell Therapy	Preclinical

Note: All drugs in current pipeline are investigational and subject to health authority approval.

The following table summarizes our discovery stage pipeline:

Target	Therapeutic Area	Vant	Modality	Phase
AR	Prostate Cancer	Proteovant	Degrader	Preclinical
STAT3	Oncology, Immunology	Proteovant	Degrader	Preclinical
Undisclosed	Oncology	Proteovant	Degrader	Discovery
CBP/p300	Oncology	Proteovant	Degrader	Discovery
SMARCA2/4	Oncology	Proteovant	Degrader	Discovery
Undisclosed	Oncology	Proteovant	Degrader	Discovery
Multiple Additional Targets	Oncology, Immunology	Proteovant	Degrader	Discovery
WRN	Oncology	Roivant Discovery	Inhibitor	Discovery
JAK2-617F	Oncology	Roivant Discovery	Inhibitor	Discovery
CRAF	Oncology	Roivant Discovery	Inhibitor	Discovery
HIF2A	Oncology	Roivant Discovery	Degrader	Discovery
ADAR1	Oncology	Roivant Discovery	Inhibitor	Discovery
STING	Immunology	Roivant Discovery	Degrader	Discovery
NLRP3	Immunology	Roivant Discovery	Degrader	Discovery
Multiple Additional Targets	Oncology, Neurology, Immunology	Roivant Discovery	Degrader	Discovery
KRAS G12D	Oncology	Proteovant, Roivant Discovery	Degrader	Discovery

Note: All drugs in current pipeline are investigational and subject to health authority approval.

The following table summarizes the opportunity profile as well as potential indications and target populations for select programs in our discovery stage pipeline at Roivant Discovery:

Target & MoA	Opportunity Profile	Potential Indications/Patient Populations
KRAS G12D Degrader	• Historically undruggable oncogene variant G12D • Most frequently mutated oncogene in human cancers	• KRAS G12D mutant tumors • Highest rates in PDAC, CRC, endometrial and lung cancer
NLRP3 Degrader	• Inflammasome; innate immune pathway target; central regulator of IL-1ß and IL-18 cytokine secretion • Drives inflammation across a broad range of chronic disorders	• Autoimmune and inflammatory diseases such as Cryoporin-associated periodic syndromes (CAPS), gout, SLE, IBD, Behcet's, and asthma
ADAR1 Inhibitor	• Intracellular innate immune checkpoint target and biomarker defined tumor cell dependency • Potential to overcome PD1/PDL1 resistance	• Type I IFN-high solid tumors including lung, colon, breast, ovarian
WRN Inhibitor	• Synthetic lethal target required in tumors with DNA damage repair deficiency	• MSI colorectal and gastric cancers
JAK2-617F Inhibitor	• Potential for precision medicine approach • Selective for mutants of blood neoplasm driver	• PARP inhibitor combinations • V617F driven myeloproliferative neoplasms: polycythemia vera, essential thrombocythemia, primary myelofibrosis and AML • NRAS mutant melanoma
CRAF Inhibitor	• Synthetic lethal target required in KRAS and NRAS mutant tumors • CRAF mutant tumors	• KRASG12X (non G12C) tumors: lung, colon, many other GIs • CRAF mutant GI cancers: gastric, colon, lung and other
HIF2A Degrader	• Synthetic lethal target required specifically in tumors with "Achilles' heel" mutation	• VHL mutant RCC • Pheochromocytoma

Note: All drugs in current pipeline are investigational and subject to health authority approval.

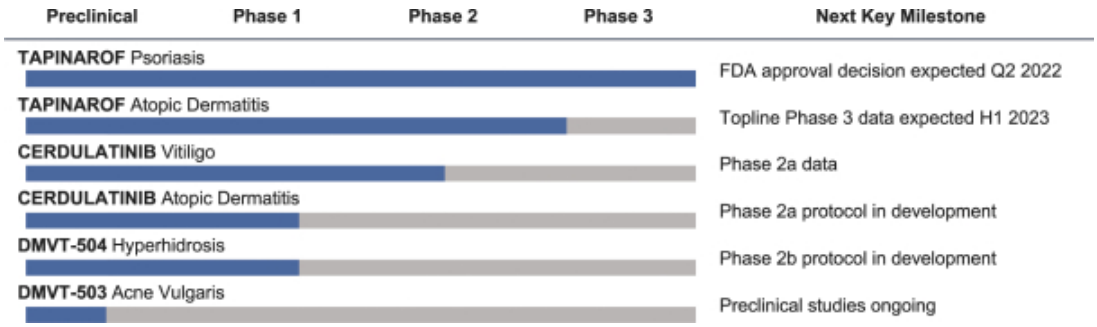
Dermavant Overview

- **Overview:**
  - Dermavant is developing tapinarof for the treatment of psoriasis and atopic dermatitis, alongside an earlier-stage development pipeline focused on multiple unmet medical needs in immuno-dermatology.
- **Lead program:**
  - Tapinarof is a novel, once daily, steroid-free topical cream in development for the treatment of plaque psoriasis and atopic dermatitis.
  - Tapinarof is a therapeutic aryl hydrocarbon receptor (AhR) modulating agent (TAMA) that directly targets the AhR, a key regulator of skin homeostasis and inflammation.
- **Disease overview:**
  - Plaque psoriasis is a chronic, inflammatory disease with skin lesions characterized by red patches and plaques with silvery scales.
  - Atopic dermatitis, the most common type of eczema, is a chronic condition characterized by dry, itchy skin.
  - Psoriasis and atopic dermatitis affect approximately 8 million and 26 million people in the United States, respectively.
- **Limitations of current treatment:**
  - Topical corticosteroids (TCS) are the most common first-line therapy but use typically cannot exceed four weeks due to risk of significant side effects.
  - While oral and biologic therapies have become increasingly available, they are often limited to moderate-to-severe psoriasis and atopic dermatitis patients that comprise the smallest percentage of the affected populations.
- **Clinical data:**
  - We completed two pivotal Phase 3 clinical trials, PSOARING 1 and PSOARING 2, for the use of tapinarof in treating mild, moderate, and severe plaque psoriasis in adults.
  - In both pivotal Phase 3 trials, which enrolled over 500 patients each, tapinarof met its primary endpoint and secondary endpoints with clinically meaningful and statistically significant responses.
  - Our long-term open-label PSOARING 3 study provides supportive evidence of tapinarof's increased therapeutic effect beyond the 12-week double-blind treatment periods, suggesting treatment durability over time, as well as supportive evidence of a remittive effect, measured by time until disease worsening following treatment discontinuation.
- **Development plan and upcoming milestones:**
  - We have filed an NDA with the FDA for tapinarof cream for the treatment of adults with plaque psoriasis and are expecting a decision on tapinarof's approval in the second quarter of calendar year 2022.
  - If approved, tapinarof would be the first novel topical therapy approved by the FDA for plaque psoriasis in over 20 years, potentially offering a favorable mix of treatment effect, safety, tolerability, durability on therapy, and remittive effect.

- In September 2021, we dosed the first patient in our Phase 3 clinical trials of tapinarof for the treatment of atopic dermatitis, ADORING 1 and ADORING 2. We expect to release topline data from ADORING 1 and ADORING 2 in the first half of calendar year 2023.

- **Roivant ownership:**
  - As of September 30, 2021, we own 100% issued and outstanding Common Shares of Dermavant and 85% on a fully diluted basis.

- **Pipeline:**



Tapinarof for the Treatment of Psoriasis and Atopic Dermatitis

Tapinarof is a novel, once daily, cosmetically elegant, steroid-free topical cream TAMA. Tapinarof directly targets the AhR, a key regulator of skin homeostasis and inflammation, to help reduce Th17 and Th2 cytokines, two pro-inflammatory pathways implicated in plaque psoriasis and atopic dermatitis, respectively, increase antioxidant activity, and promote skin barrier restoration. Tapinarof cream is designed to be easy to apply, non-greasy and odorless, which we believe makes it cosmetically elegant. To date, over 2,200 subjects have been enrolled in 18 clinical trials of tapinarof and predecessor formulations of tapinarof cream.

Psoriasis and atopic dermatitis

Psoriasis and atopic dermatitis (“AD”) affect hundreds of millions of people globally each year, impacting their quality of life, including their physical health, psychological state, and overall well-being. While topical therapies are the foundation of treatment, many patients fail to achieve their desired outcome due to subpar efficacy, tolerability and safety concerns, application site restrictions and limits on duration of therapy.

Psoriasis is a chronic, inflammatory disease with skin lesions characterized by red patches and plaques with silvery scale that affects an estimated 8 million people in the United States. Its most common form, psoriasis vulgaris or plaque psoriasis, constitutes approximately 80 to 90% of all cases of psoriasis. Psoriasis severity is typically classified by body surface area (“BSA”) involvement: mild (less than 3% BSA), moderate (3% to 10% BSA) and severe (greater than 10% BSA). Based on this guideline, approximately 80% of patients with psoriasis in the United States have mild to moderate disease, which is most often amenable to topical treatment. Common signs and symptoms of psoriasis include itching and burning, which can be very intense and frequent. Other symptoms can include cracking and bleeding of the skin. Psoriasis can cause significant social and emotional distress.

Atopic dermatitis is the most common type of eczema, affecting more than 9.6 million children and about 16.5 million adults in the United States. It is a chronic condition characterized by dry, itchy skin that often turns into a red rash. Atopic dermatitis can come and go for years or throughout life and can overlap with other types

of eczema. Atopic dermatitis has a complex pathophysiology involving genetic, immunologic and environmental factors, culminating in skin barrier dysfunction and immune system dysregulation. The condition occurs most
frequently in children (15 to 30% worldwide). Approximately 60% of those who develop atopic dermatitis show symptoms in the first year of life and up to 90% show symptoms by five years of age. While more prevalent in infancy and adolescence, one in ten people will develop atopic dermatitis. Approximately 89% of adult patients have mild to moderate atopic dermatitis, while 11% have severe atopic dermatitis. Atopic dermatitis is associated with several comorbidities, including asthma, allergies depression, and sleep disruption, and could negatively impact quality of life.

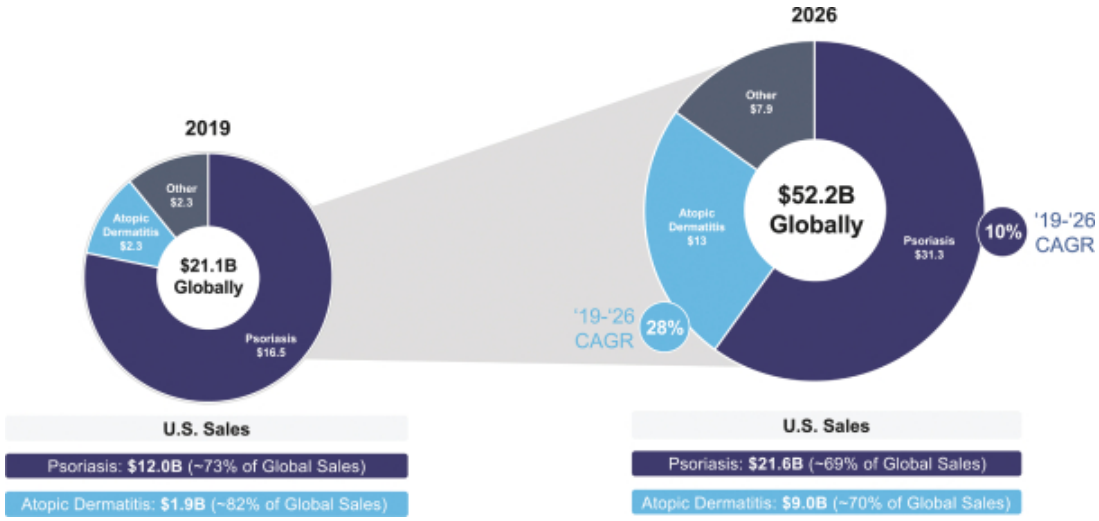
While topical therapies are the foundation of treatment, many patients fail to achieve their desired outcome due to subpar efficacy, tolerability and safety concerns, application site restrictions and limits on duration of therapy. Topical corticosteroids ("TCS") are commonly used as the first-line therapy for the treatment of inflammatory skin conditions, such as psoriasis and atopic dermatitis. They are broadly available in generic form and carry FDA class labeling that restrict their duration of use, typically to no more than four weeks, and their location of use, prohibiting use in sensitive skin areas such as the face, groin, or axillae (armpit). While many people experience improvement with TCS, the continual long-term use of TCS has the potential to cause significant side effects including skin atrophy. As a result, healthcare professionals and patients are limited to intermittent treatment cycles of TCS therapy, leading to frequent disease flares and recurrence of disease, providing an inadequate solution for chronic conditions in immuno-dermatology. Topical calcineurin inhibitors ("TCI") are an additional non-steroidal option for the topical treatment of atopic dermatitis, but their use is limited by safety concerns, including boxed warnings of malignancy reported in patients treated with TCIs. Oral and biologic therapies have become increasingly available but are often limited to moderate-to-severe psoriasis and atopic dermatitis patients which comprise the smallest percentage of the affected populations. While biologics have proven to be very effective, their use has also been limited by concerns with systemic side effects, high cost, and reimbursement and access restrictions. Oral therapies are functionally limited to moderate-to-severe psoriasis patients. Oral therapies also have significant side effects and have not achieved the same level of efficacy as biologics. Additionally, recent FDA action regarding Janus kinase inhibitors ("JAKs") have resulted in restrictive labeling and black box warnings relating to safety concerns with the product class, including oral and topical forms, and including for the topical treatment of atopic dermatitis.

Given the limitations associated with TCS, other topicals, orals, and biologics therapies, patients with inflammatory skin conditions often report dissatisfaction with their current treatment options.

Psoriasis and atopic dermatitis represent the two largest markets in immuno-dermatology and are expected to reach total sales of approximately $31 billion in the U.S. and $44 billion globally by 2026. Topical treatments serve as the foundation of dermatologic treatment, representing 83% of all U.S. prescriptions written by dermatologists in 2020. Additionally, we believe that tapinarof has the potential to be prescribed alongside biologics and oral therapies. Annual U.S. prescriptions for both psoriasis and atopic dermatitis are outlined below:

	TCS	Vitamin D / Combos / Retinoids	Biologics	Otezla	Other Oral
Annual Scripts for PsO (2020)	~2.35M	~508K	~1.05M	~258K	~241K

	TCS	TCI	Eucrisa	Dupixent
Annual Scripts for AD (2020)	~16.4M	~996K	~352K	~344K



Source: EvaluatePharma

Tapinarof for the Treatment of Psoriasis

Clinical data

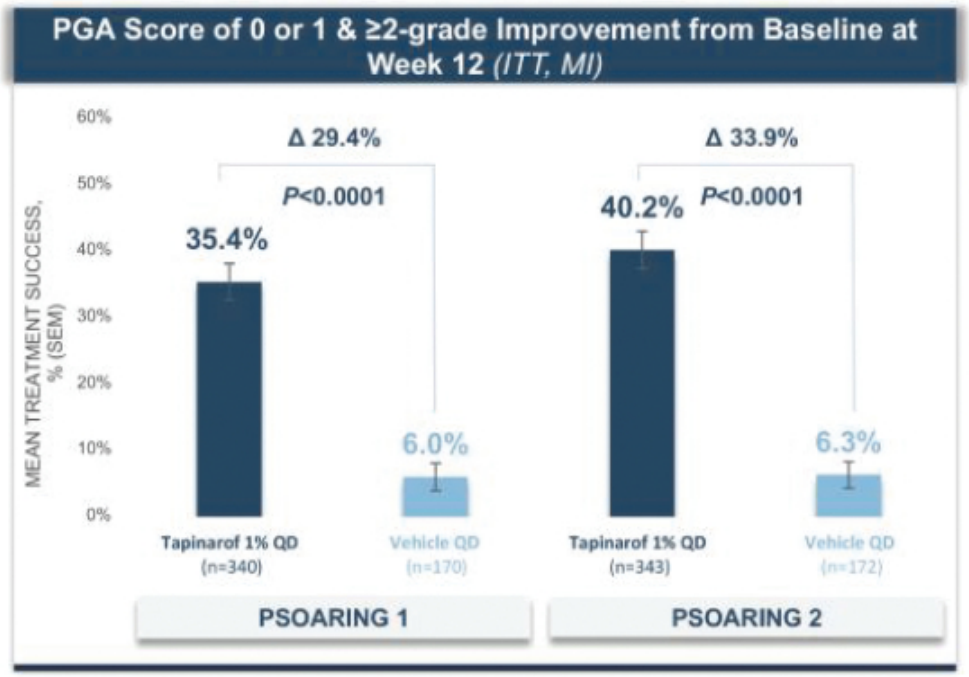
We completed two pivotal Phase 3 clinical trials, PSOARING 1 and PSOARING 2, evaluating the use of tapinarof in treating mild, moderate and severe plaque psoriasis in adults. In both of these trials, which enrolled over 500 patients each, tapinarof met its primary endpoint and all secondary endpoints with clinically meaningful and statistically significant responses as well as favorable safety and tolerability findings. At week 12, 35.4% and 40.2% of patients treated with tapinarof in PSOARING 1 and PSOARING 2, respectively, achieved the primary efficacy endpoint of a Physician Global Assessment (PGA) score of clear (0) or almost clear (1) with a minimum 2-grade improvement from baseline as compared to 6.0% and 6.3% of patients treated with vehicle cream ($p<0.0001$; $p<0.0001$). When this endpoint was evaluated over time, rapid onset of activity was observed with separation emerging by the first evaluation trial visit (week 2) and statistically significant differences between tapinarof and vehicle cream at week 4 and continuing at all measured time points thereafter.

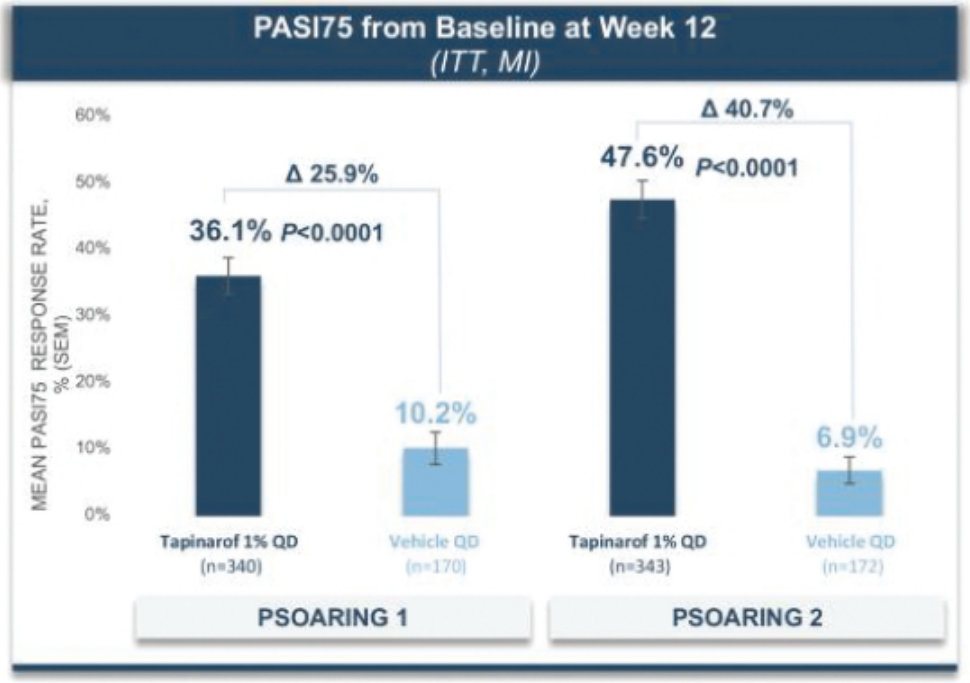
Tapinarof met all secondary endpoints with statistical significance in PSOARING 1 and PSOARING 2, including a key secondary endpoint, the proportion of subjects with ³75% improvement in Psoriasis Area and Severity Index (PASI75). In PSOARING 1 and 2, 36.1% and 47.6% of patients achieved PASI75 at Week 12 with tapinarof 1% cream QD vs 10.2% and 6.9% for vehicle, respectively. Additionally, the proportion of patients with ³90% improvement in Psoriasis Area and Severity Index (PASI90) at Week 12, also a secondary endpoint, was statisticially significantly higher in both tapinarof groups compared with vehicle cream ($p=0.0005$ and $p<0.0001$). 18.8% and 20.9% of patients treated with tapinarof in PSOARING 1 and PSOARING 2, respectively, achieved PASI90 compared to 1.6% and 2.5% of patients treated with vehicle cream. The PASI assessment is a more quantitative assessment of disease activity relative to the PGA and provides additional insight into a drug's impact on disease modification. Similar to what was observed with PGA, evaluating reduction in the burden of disease via a PASI assessment confirms rapid onset of action with separation of tapinarof from vehicle cream control at week 2, and statistically significant differences were noted as early as week 4 and each evaluation thereafter.

Additionally, tapinarof was observed to be well-tolerated, consistent with previous trials, and had low discontinuation rates due to adverse events ("AEs"), no treatment related serious adverse events ("SAEs"), and minimal severe application site reactions.

Tapinarof was observed to be well-tolerated in both trials, with AEs generally mild to moderate in nature and the majority consisting of localized skin reactions. Overall trial discontinuations due to adverse events were
5.6% in PSOARING 1 and 5.8% in PSOARING 2. Trial discontinuation rates due to folliculitis were 1.8% in PSOARING 1 and 0.9% in PSOARING 2. No tapinarof-related severe adverse events were observed, and over 90% of eligible patients enrolled in the long-term extension study. To date, over 2,200 subjects have been enrolled in 18 clinical trials of tapinarof and predecessor formulations of tapinarof cream.

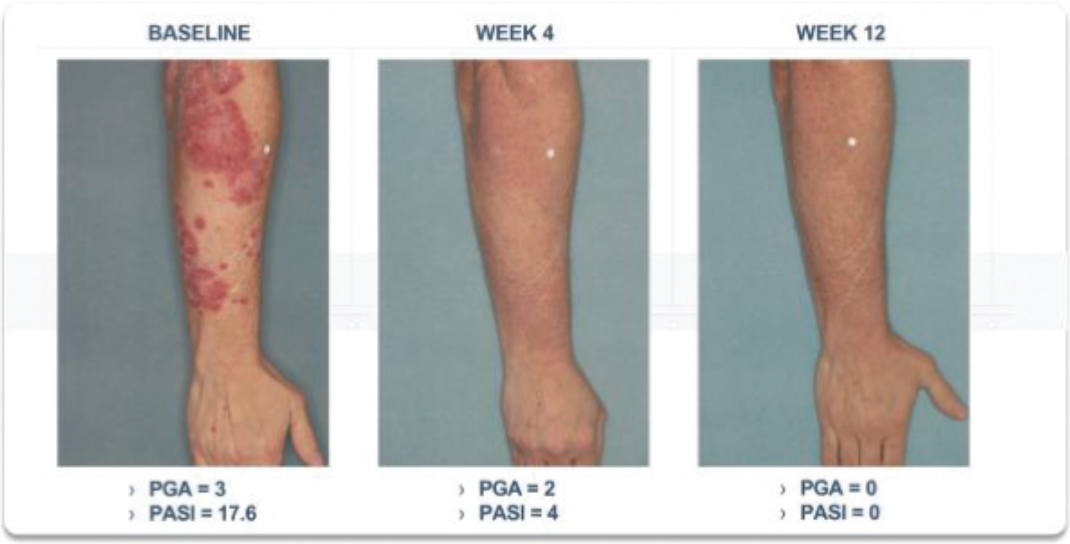
* Patients with PGA of 2 (mild) and PGA of 4 (severe) limited to ~10% each of the total randomized population;~80% of the total randomized population with PGA of 3 (moderate); †Patients electing not to participate in LTE had follow-up visit 4 weeks after completion of treatment period. BSA, body surface area; LTE, long-term extension; PASI75, [3] 75% improvement in Psoriasis Area and Severity Index; PASI90, [3] 90% improvement in Psoriasis Area and Severity Index; PGA, Physician Global Assessment; QD, once daily. 1. Clinicaltrials.gov; NCT03956355. 2. Clinicaltrials.gov; NCT03983980. 3. Clinicaltrials.gov; NCT04053387.





Patients, n (%)	PSOARING 1		PSOARING 2	
	Tapinarof 1% QD (n=340)	Vehicle QD (n=170)	Tapinarof 1% QD (n=343)	Vehicle QD (n=172)
TEAE	171 (50.3)	38 (22.4)	187 (54.5)	45 (26.2)
Mild	76 (22.4)	16 (9.4)	80 (23.3)	17 (9.9)
Moderate	82 (24.1)	22 (12.9)	98 (28.6)	28 (16.3)
Severe	11 (3.2)	0 (0.0)	8 (2.3)	0 (0.0)
Serious TEAE	9 (2.6)	0 (0.0)	7 (2.0)	0 (0.0)
Study discontinuation due to AEs	19 (5.6)	0 (0.0)	20 (5.8)	1 (0.6)
Most common treatment related TEAEs (≥1% in any group)				
Folliculitis	70 (20.6)	2 (1.2)	54 (15.7)	1 (0.6)
Contact dermatitis	13 (3.8)	1 (0.6)	16 (4.7)	0 (0.0)
Headache	5 (1.5)	1 (0.6)	1 (0.3)	0 (0.0)
Pruritus	4 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)
Dermatitis	1 (0.3)	0 (0.0)	4 (1.2)	0 (0.0)
Study discontinuation due to AESI				
Folliculitis	6 (1.8)	0 (0.0)	3 (0.9)	0 (0.0)
Contact dermatitis	5 (1.5)	0 (0.0)	7 (2.0)	0 (0.0)
Headache	1 (0.3)	0 (0.0)	2 (0.6)	0 (0.0)
Severity of folliculitis, n (%) among subset of patients with AESI of folliculitis				
Mild	51 (63.8)	1 (50.0)	44 (72.1)	0 (0.0)
Moderate	28 (35.0)	1 (50.0)	17 (27.9)	1 (100.0)
Severe	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

The below figure shows rapid and complete clearance of plaque psoriasis in a patient achieving the defined trial endpoint. At baseline, this patient's PGA score was 3, indicative of moderate disease, and the PASI score was 17.6. The baseline image demonstrates classic plaque psoriasis with well demarcated erythematous scaling plaques. At week 4, the PGA had decreased from 3 to 2 and the PASI from 17.6 to 4, the latter having passed the threshold 75% reduction in PASI (PASI75). The target plaques on the forearm are completely resolved. At week 12, both the PGA and PASI scores were 0, indicating complete clearance of disease. PGA and PASI are global efficacy assessments.



In September 2021, we reported the final results from our long-term open-label study, PSOARING 3, which showed that 58.2% of subjects who entered the PSOARING 3 study with a PGA score of ³ 2 achieved a PGA score of 0 or 1 at least once during the study. Although PSOARING 3 was not a vehicle-controlled study unlike the prior two PSOARING studies, we believe these data provide supportive evidence regarding tapinarof's potential therapeutic effect beyond the 12-week doubleblind treatment periods utilized in PSOARING 1 and PSOARING 2. In addition, 312 out of 763 subjects (40.9%) achieved complete disease clearance (PGA score of 0) at least once during the study. We observed no evidence of tachyphylaxis, or a diminishing response to treatment, throughout the study, which we believe suggests treatment durability over time.

At the time of an interim analysis of PSOARING 3 open-label study results in February 2021, we completed an integrated summary of efficacy (ISE) that included data from PSOARING 1, PSOARING 2 and the PSOARING 3 interim analysis summary from subjects with a PGA score of ³ 2 prior to tapinarof administration. In the integrated analysis, we identified a PGA response of clear (0) or almost clear (1), plus at least a 2-grade improvement from baseline, at any time point, in 57% of subjects, PASI75, at any time point, in 63.5% of subjects, and PASI90, at any time point, in 44.2% of subjects, providing evidence of improvement beyond the 12 week double-blind treatment period.

In our pivotal Phase 3 clinical trials, we observed that tapinarof's treatment effect did not decline with continued use over the duration of the trials, which we refer to as durability on therapy. While statistically significant differences in favor of tapinarof were observed in the 12-week, double-blind studies, in our open-label, single-arm PSOARING 3 long-term study, continued improvement was observed in both PGA and PASI beyond 12 weeks with continued use of tapinarof. This observation of continued improvement in reducing disease burden (durability on therapy) was evidenced by the number of patients who achieved complete disease clearance at 12 weeks (n=79) and with continued use beyond 12 weeks, an additional 233 patients achieved complete disease clearance, indicating no evidence of loss of treatment effect over time.

Relatedly, in our clinical trials we have also observed, including data from our PSOARING 3 long-term open-label study, that some patients treated with tapinarof maintained clinically meaningful disease control for an extended period of time after therapy had been discontinued. In PSOARING 3, subjects discontinued applying tapinarof when they achieved complete clearance of their disease (PGA=0). These subjects were then followed, and the time to first worsening (defined as PGA ³ 2) was utilized to determine the maintenance of clinical benefit off therapy, and we refer to maintenance of clear/almost clear (PGA 0/1) while off therapy as remittive effect. At

the completion of the Week 12 visit of the PSOARING 1 and PSOARING 2 trials, subjects were offered enrollment in the PSOARING 3 long-term open-label study. Subjects with a PGA ³ 1 began treatment with tapinarof cream applied QD until they achieved a PGA score of 0. Treatment was discontinued when a subject achieved a PGA score of 0 and re-initiated for subsequent worsening disease (PGA ³ 2).

In PSOARING 3, for subjects entering the study with a PGA score of 0 (79/763), the median time to disease worsening (defined as a PGA score of ³ 2) following complete disease clearance and treatment discontinuation was approximately 115 days. In addition, among patients entering PSOARING 3 with or achieving a PGA score of 0 (312/763), the mean total duration of time to disease worsening following treatment discontinuation was approximately 130 days.

Development plan

We have filed an NDA with the FDA for tapinarof cream for the treatment of adults with plaque psoriasis and are expecting a decision on tapinarof's approval in the second quarter of calendar year 2022. Tapinarof has the potential to be the first novel topical therapy approved by the FDA for plaque psoriasis in over 20 years.

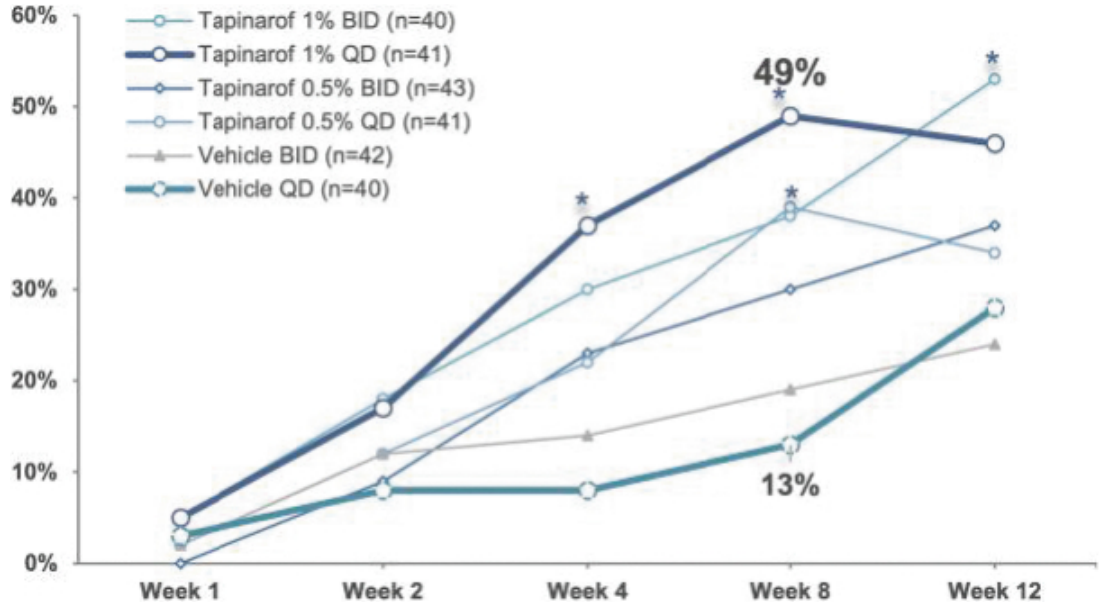
Tapinarof for the Treatment of Atopic Dermatitis

Clinical data

In 2017, GSK completed a multicenter randomized, double-blind, vehicle cream-controlled Phase 2b clinical trial of tapinarof for the treatment of atopic dermatitis in 247 adult (aged 18 to 65 years) and adolescent (aged 12 to 17 years) patients. Patients were randomized equally to six treatment groups: tapinarof cream 0.5%, tapinarof cream 1% or vehicle cream, each applied to atopic dermatitis lesions either QD or BID. The primary endpoint was the percentage of patients who achieved a minimum two-point improvement in IGA score and resulted in an assessment of "clear" or "almost clear" skin at week 12. These cases were considered a "treatment success." Secondary endpoints included the percentage of patients with at least 75% improvement in Eczema Area and Severity Index (EASI) from baseline. Efficacy was evaluated in the intent to treat (ITT) population.

Overall, the percentage of patients achieving treatment success at week 12 was much higher than vehicle cream for both tapinarof concentrations, with a robust dose response. Treatment success at week 12 was higher for both tapinarof concentrations when compared with vehicle cream. 53% of patients who applied tapinarof cream 1% BID and 46% of those who applied it QD were considered a treatment success at week 12. This compares favorably to the 24% and 28% levels for vehicle cream BID and QD, respectively. At week 12, 60% and 51% of patients treated with tapinarof cream 1% BID and QD, respectively, achieved EASI75. The treatment effect across adults and adolescents was observed to be consistent. Patient-reported outcome data was collected during the Phase 2b clinical trial, including data on reduction in severity of pruritus. At week 12, most patients treated with tapinarof cream 1% (78% of patients treated BID and 87% of patients treated QD) reported "moderately improved" to "very improved" pruritus, compared to patients treated with vehicle cream (47% of patients treated BID and 64% of patients treated QD).

IGA score 0 or 1 and ³2-grade improvement at Week 8
Primary Endpoint was at 12 Weeks: Assessed in ITT Population (NRI Analysis)



IGA response: IGA score of 0 or 1 and a ³2-grade improvement from baseline.

* *Difference versus vehicle cream is statistically significant at p=0.05 level (the 95% confidence interval excludes 0).*

Tapinarof was observed to be well-tolerated in this Phase 2b trial for atopic dermatitis, with the majority of AEs reported as mild or moderate in intensity. In the trial, TEAEs were considered treatment-related in 10% to 19% of dosed patients across the treatment arms. The most commonly reported TEAEs were folliculitis, application-site pain and atopic dermatitis. TEAEs led to permanent discontinuation of trial treatment in 4% of dosed patients (seven patients from treatment groups total) compared to 7% of patients receiving vehicle cream (six patients total). Only one patient (tapinarof 1% BID) experienced a SAE of anxiety and hyperactive disorder, which was not considered to be related to treatment.

Development plan

We recently initiated ADORING 1 and ADORING 2, two identically designed, multi-center, randomized, vehicle-controlled, double-blind parallel Phase 3 clinical trials of tapinarof for the treatment of atopic dermatitis, and we dosed the first patient in September 2021. We expect to release topline data from ADORING 1 and ADORING 2 in the first half of calendar year 2023. The two trials will enroll up to 800 patients across both trials to evaluate the safety and efficacy of tapinarof cream, 1% dosed once daily (QD) for 8 weeks versus vehicle cream QD in patients aged 2 years and older diagnosed with moderate to severe atopic dermatitis. The primary endpoint of both studies will be the percentage of patients achieving a Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™), of 0 or 1 with at least a 2-grade improvement from baseline at week 8.

Additionally, we have initiated ADORING 3, a long-term, open-label, extension study to evaluate the safety and efficacy of tapinarof cream, 1% in patients with atopic dermatitis. Subjects in the study will include those who have previously completed treatment with tapinarof or vehicle in ADORING 1 or ADORING 2, as well as subjects who have completed a maximal use PK study, and those pediatric subjects who would not qualify for inclusion in ADORING 1 or 2 due to milder or more severe disease. ADORING 3 will consist of up to 48 weeks of tapinarof cream, 1%, and a 7-day safety follow-up period.

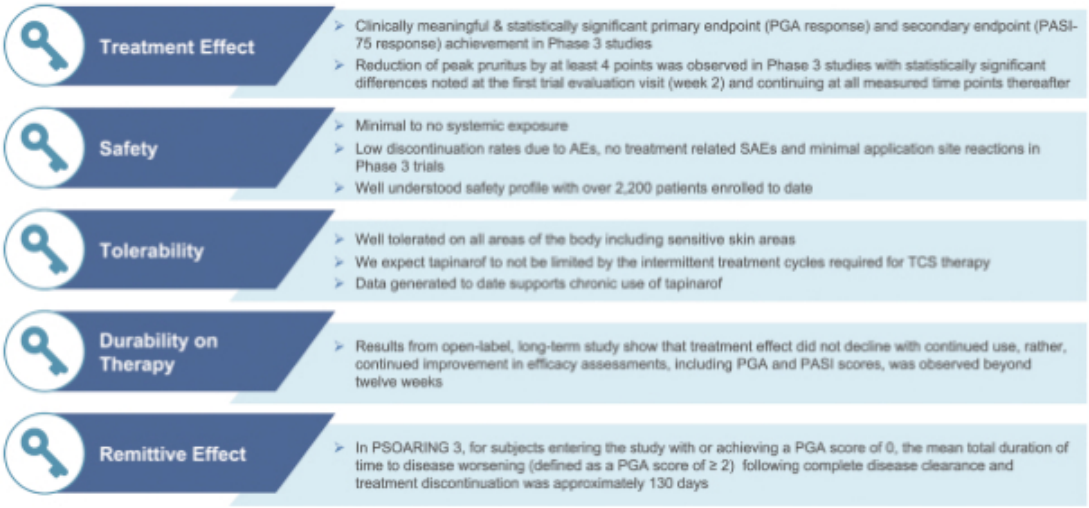
Potential Benefits of Tapinarof—Limitations of Current Treatments

Tapinarof's potential in psoriasis

While TCS, especially high potency TCS, are the most commonly prescribed first line topical agents for plaque psoriasis treatment, continual and long-term TCS treatment carries the risk of a variety of significant side effects, as well as the inability to utilize them in sensitive skin areas (e.g., areas such as the face, groin, or axillae), and is associated with HPA axis suppression, skin atrophy (thinning), striae (stretch marks), and telangiectasia (spider veins), among other side effects. Furthermore, some of these side effects are irreversible, persisting even after therapy is discontinued. Consequently, high-potency TCS are not recommended for chronic use, and physicians generally will not prescribe them for treatment on the face or in the intertriginous regions where skin opposes skin, such as skin folds. For example, the label for clobetasol propionate, the most commonly used high-potency steroid, limits use to two consecutive weeks, and use on the face or intertriginous regions is contraindicated. Facial psoriasis affects 33%-50% of psoriasis patients, and between 21%-30% of people living with psoriasis develop intertriginous psoriasis.

Oral and biologic therapies are also available but are only indicated for a small percentage of the affected population, are expensive and often face access and reimbursement restrictions. While highly efficacious, biologic therapies may require frequent injections and regular physician appointments, have potential systemic toxicities and often require laboratory monitoring. As a result, use of biologics remains limited to patients with significant disease burden. Patients on biologics often continue to use TCS on resistant patches and plaques. Oral therapies have not yet achieved the same level of efficacy as biologics, but also have potential systemic side-effects, often requiring dose titration to mitigate adverse reactions. Systemic exposure to PDE4 inhibitors has been linked to depression and suicidal ideation. For example, the FDA labeling for both Otezla, the leading branded oral PDE4 inhibitor, and roflumilast, recommends advising patients to be alert for the emergence or worsening of suicidal thoughts or other mood changes, and indicates that instances of suicidal ideation and behavior were observed in clinical trials. In addition, Otezla requires dosing twice daily (BID), which can compromise adherence to the treatment regimen. Despite inferior efficacy compared to biologics, oral therapies comprise significant market share. Otezla generated over $2 billion in worldwide sales in psoriasis and psoriatic arthritis in 2020, indicating a need for more convenient treatment options with efficacy across the disease spectrum of mild to severe. In two Phase 3 trials in psoriasis patients, 20% and 22% of patients on oral Otezla achieved a PGA response at week 16, vs. 4% and 4% for placebo, respectively.

We believe tapinarof's differentiated clinical profile has five key attributes that will position it favorably over current standard of care treatments in psoriasis, including TCS therapies, if approved.



We have commissioned robust qualitative and quantitative prescriber, payor and patient third party market research, involving more than 500 health care providers, more than 300 patients and 65 payors. Based on this market research, we believe that an unmet need exists in psoriasis for a safe and conveniently administered non-steroidal topical therapy that can be applied without interruption or long-term safety concerns and has potential efficacy similar to that of TCS and some systemically administered products. If approved, such a treatment could provide a significant improvement for those patients who do not receive adequate relief from current topical therapies or who have reservations about the safety and cost of oral medications or biologics or are unable to access these therapies. Our market research indicates that payors perceive tapinarof as a novel therapy that, if approved, could provide the potential to arrest the increasing cost trend of the psoriasis category, based on a survey of 15 payors. If approved, tapinarof could give national payors the opportunity to reduce spend in the overall psoriasis therapeutic class while allowing physicians and patients access to a potentially highly potent, safe, and tolerable treatment option for plaque psoriasis before moving to more costly oral and biologic therapies. TCS, due to their FDA label safety limitations, do not allow payors the versatility to aggressively manage a chronic condition in a manner that can effectively control the psoriasis therapeutic category cost trend.

Based the clinically meaningful and statistically significant reduction in psoriasis symptoms tapinarof demonstrated in both Phase 3 trials, coupled with safety data, we believe tapinarof could be used broadly without restriction on skin application sites, or duration of use if approved. We believe the Phase 3 data we have generated and the data observed in our open-label, long-term extension study support the chronic use of tapinarof, potentially in place of other topical and oral treatments, for the treatment of mild, moderate and severe plaque psoriasis, if approved.

Tapinarof's potential in atopic dermatitis

TCS, especially low-to-mid potency TCS, represent the standard-of-care for atopic dermatitis treatment. Although they are used commonly, TCS pose a specific concern in pediatric patients due to the risk of systemic absorption, HPA axis suppression, skin thinning and other potential side effects. The increased body surface area to mass ratio in children results in increased absorption and systemic exposure. The American Academy of Dermatology guidelines suggest limiting long-term use of TCS in children to avoid the risk of systemic side effects. As such, 86% of U.S. patients report dissatisfaction with current treatment options for atopic dermatitis according to the National Eczema Association. There is also considerable concern among many parents about treating their children with steroids, which can be an obstacle to treatment for physicians. Due to these risks and patient dissatisfaction, health care providers are less likely to use them long-term in children and also in sensitive skin areas such as the face or diaper/groin area. In addition, topical PDE4 inhibitors developed to treat atopic dermatitis have been associated with side effects including application site burning and stinging. Topical calcineurin inhibitors are an additional non-steroidal option for the topical treatment of atopic dermatitis; however, their use has been limited by safety including boxed warnings of malignancy (e.g., skin and lymphoma) having been reported in patients treated with topical calcineurin inhibitors.

Patients whose disease flares despite topical treatments may be prescribed systemic agents such as oral corticosteroids or oral cyclosporine to rapidly relieve severe signs and symptoms of the disease. While these are effective as temporary treatments of flare-ups, extended use has been associated with many potential side effects or adverse events. Systemic steroids, such as prednisone, can lead to symptom relief, but their use is not recommended to induce stable remission due to numerous side effects associated with steroids and the propensity of severe disease flares upon abrupt treatment cessation. Cyclosporine is also generally not recommended for use lasting longer than one to two years, as it has been associated with renal toxicity, hirsutism, nausea and lymphoma. Based on data from the 2014 Adelphi U.S. AD Disease Specific Program, over 58% of adults with moderate-to-severe atopic dermatitis have disease which physicians consider to be inadequately controlled by these therapeutic modalities. While biologic therapies are more efficacious, as is the case in psoriasis, use of therapies such as the recently approved Dupixent is limited to patients with significant disease burden as they are

expensive, necessitate frequent injections, entail regular physician appointments, have potential systemic toxicities and often require laboratory monitoring. Additionally, recent
FDA action regarding JAKs have resulted in restrictive labeling and black box warnings relating to safety concerns with the product class, including oral and topical forms, and including for the topical treatment of atopic dermatitis.

We believe tapinarof has the potential to fill the need for a long-term treatment option for atopic dermatitis. We also believe that tapinarof has the potential to offer significant clinical advancement to address the incessant flare cycle experienced by atopic dermatitis patients that is the result of the short-term use limitation of standard-of-care TCS.

Since acquiring tapinarof in 2018, we have expanded our intellectual property with multiple patents, which are expected to expire beginning in 2036.

Tapinarof sales and marketing

If tapinarof is approved by the FDA for the treatment of mild, moderate or severe plaque psoriasis, we intend to commercialize it in the United States by building a highly specialized commercial sales organization focused on high value dermatology healthcare providers and their patients and implementing a “best-in-class” payor reimbursement and patient point of sale access strategy, which we believe will ensure broad patient access at launch.

As psoriasis patients are predominantly managed by dermatologists, we intend to deploy a specialty sales team focused on a core target base of top-decile dermatologists who write more than 80% of all commercial prescriptions in the psoriasis market. We believe a scientifically oriented, customer-focused team of approximately 75 to 100 sales representatives will allow us to reach the approximately 6,000 highest value dermatology healthcare providers. For markets outside of the U.S., we may opportunistically seek strategic collaborations to maximize the commercial opportunities for tapinarof.

If tapinarof or topical cerdulatinib are approved by the FDA for the treatment of atopic dermatitis, we plan to expand our psoriasis sales team to be able to reach additional specialists who see a significant amount of atopic dermatitis patients, such as pediatric dermatologists and allergists. Based on our commercial team’s experience developing and launching dermatology products in U.S., we believe we can effectively reach the psoriasis and atopic dermatitis core target base with a highly specialized sales team of 125 to 150 total sales representatives.

Earlier-Stage Pipeline

Beyond tapinarof, Dermavant’s pipeline consists of three novel product candidates targeting an array of significant unmet medical needs in the field of dermatology.

Cerdulatinib (DMVT-502)

We are evaluating topical cerdulatinib as a differentiated dual inhibitor of the JAK and Syk pathways. Given its unique mechanism of action, we believe that topical cerdulatinib, if approved, could provide a differentiated treatment option for vitiligo, a condition for which there are no FDA approved treatments that suppress vitiligo disease activity, as well as other inflammatory skin conditions that have already been validated for JAK inhibition, such as atopic dermatitis. We initiated a Phase 2a clinical trial of topical cerdulatinib for the treatment of vitiligo in 2019 and received top-line results in the first half of 2021 that met the primary endpoints of safety and tolerability.

Vitiligo is an inflammatory skin condition characterized by skin depigmentation resulting from the loss of skin melanocytes. It usually involves the face, digits, arms, inguinal area, anogenital area, umbilicus and nipples, and can also affect the hair. Affected patches of skin are sharply demarcated and noticeable, particularly among
patients with a darker natural skin color. Vitiligo is the most common skin depigmentation (color loss) disorder, affecting up to 1% of people of all ages, sexes, and ethnicities, worldwide. Vitiligo can severely impact patients' quality of life and psychological well-being due to its appearance and visibility, which can each persist for the duration of a patient's life.

Based on preclinical data observed to date, we believe topical cerdulatinib's dual JAK/Syk inhibition has the potential to be a powerful combination for the treatment of vitiligo. In a mouse model of vitiligo, the effect of cerdulatinib (dosed orally QD) on epidermal depigmentation and melanocyte-specific immunity was evaluated versus placebo over a five-week span. We observed a significant decrease in vitiligo scores compared with placebo at doses of 30 mg/kg (p=0.0003) and 60 mg/kg (p=0.0001). The drug prevented epidermal depigmentation in the mice and was associated with a significant reduction of melanocyte-specific T cells in skin tissues. Topical administration has the potential to avoid systemic toxicities that are often associated with oral JAK inhibitors.

Given topical cerdulatinib's unique dual JAK/Syk inhibitor mechanism of action, we believe it also has the potential to offer particular advantages for the treatment of atopic dermatitis. In a preclinical mouse model of atopic dermatitis, contact sensitization is experimentally induced via the application of dinitrochlorobenzene. Syk knockout mice are resistant to this chemically-induced contact dermatitis. By blocking Syk activity, topical cerdulatinib may suppress the role that exogenous contact antigens play in the activity and flares associated with atopic dermatitis. Inhibiting both pathways simultaneously has the potential to not only control inflammatory disease activity but also to reduce flare frequency.

We conducted a Phase 1 trial to investigate the safety, tolerability and PK profile of topical cerdulatinib over a 14-day trial period in healthy volunteers and adults with atopic dermatitis. The results showed reductions in atopic dermatitis disease activity and evidence of drug-target engagement via biomarkers. Measures of epidermal hyperplasia showed improvements from treatment with topical cerdulatinib. Gene expression of immune markers was also reduced, which correlated with improvement in clinical response. Topical cerdulatinib gel 0.37% was generally observed to be well-tolerated among patients in this trial, with no serious AEs reported or trial discontinuations.

DMVT-504

DMVT-504 is an investigational oral candidate that we are developing for the treatment of primary focal hyperhidrosis (PFH). DMVT-504 combines an immediate-release muscarinic antagonist, oxybutynin, with a delayed-release muscarinic agonist, pilocarpine, designed to mitigate dry mouth typically observed with anticholinergic therapies for better long-term tolerability.

Primary focal hyperhidrosis is a condition characterized by excessive sweating—beyond what is physiologically required by the body or what is expected given the local environment and temperature. The most common focal areas affected by the disease are the underarms, palms of hands, soles of feet, and face. Approximately 80% of patients experience symptoms in multiple areas of the body, with 70% of patients reporting excessive sweating in multiple areas. Hyperhidrosis results in substantial impairments for patients; excessive sweating, which can range from mild to "dripping," can severely limit social interactions, work productivity and physical activity. Hyperhidrosis has an estimated prevalence in the United States of 4.8%, representing approximately 15.3 million people, half of whom are reportedly undiagnosed.

In a Phase 2a proof-of-concept clinical trial conducted by TheraVida, Inc. (TheraVida) in patients with PFH, THVD-102 (a predecessor formulation of DMVT-504) significantly reduced Hyperhidrosis Disease Severity Score (HDSS) compared with placebo (p=0.04) and was also able to provide a statistically significant reduction

(p=0.027) in dry mouth symptoms. In connection with additional formulation work, we have completed a Phase 1 clinical trial to investigate the safety, tolerability and PK profile of multiple formulations of DMVT-504. All formulations of DMVT-504 assessed in the study were observed to be generally well-tolerated, and mean PK results showed a relationship between formulation and delayed-release characteristics.

Given the site-specific nature of treating hyperhidrosis, we believe patients would benefit from an oral therapy that provides a non-invasive treatment approach with a simple dosing regimen, efficacy across multiple focal sites of excessive sweating, and limited side effects commonly associated with oral and biologic anti-cholinergic therapies.

DMVT-503

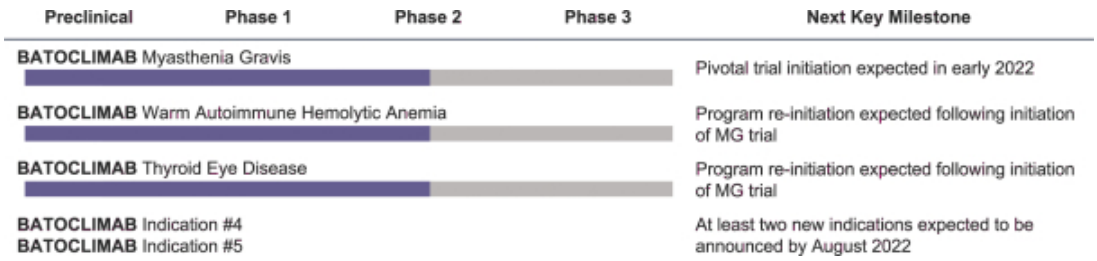
In addition to its clinical pipeline, Dermavant is developing DMVT-503, a topical DGAT1 inhibitor, as a treatment for acne vulgaris. We are conducting a pre-clinical mouse model study to explore the potential for DMVT-503 to induce dose-dependent atrophy of sebum-producing sebaceous glands, a similar effect to and potential biomarker of isotretinoin efficacy.

Immunovant Overview

- **Overview:**
  - Immunovant is developing batoclimab for the treatment of Myasthenia Gravis ("MG"), Warm Autoimmune Hemolytic Anemia ("WAIHA") and Thyroid Eye Disease ("TED").
- **Lead program:**
  - Batoclimab is a novel, fully human monoclonal antibody that selectively binds to and inhibits the neonatal fragment crystallizable receptor ("FcRn").
  - Designed to be a fixed-dose, self-administered subcutaneous ("SC") injection on a convenient weekly, or less frequent, dosing schedule.
  - In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce immunoglobulin G ("IgG") antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in related disease areas.
- **Disease overview:**
  - Advanced IgG-mediated autoimmune diseases had an aggregate prevalence of approximately 758,000 patients in 2020 in the United States and Europe.
  - MG is a rare autoimmune disorder characterized by weakness of muscles including ocular, head, oropharyngeal, limb and respiratory muscles and affected an estimated 66,000 people in the U.S. in 2020.
  - WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells ("RBCs"), affecting approximately 42,000 patients in the U.S. and 67,000 patients in Europe.
  - TED is most commonly caused by IgG autoantibodies that active cell types present in tissues surrounding the eye and can ultimately be sight-threatening and has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe.
- **Limitations of current treatments:**
  - Early-stage disease: corticosteroids and immunosuppressants
  - Later-stage disease: intravenous immunoglobulin ("IVIg"), or plasma exchange
  - Approaches are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles
- **Clinical data:**
  - In February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and low-density lipoprotein ("LDL") levels observed in some trial subjects treated with batoclimab and informed regulatory authorities and trial subjects and investigators of this voluntary pause of dosing in our studies that were ongoing at that time. Following a program-wide data review from February 2021 through May 2021 suggesting that lipid elevations are predictable, manageable, and appear to be driven by reductions in albumin, we plan to resume clinical development of batoclimab in MG, TED and WAIHA.
  - Statistically significant improvements on the Myasthenia Gravis Activities of Daily Living ("MG-ADL") scale and Myasthenia Gravis Composite ("MGC") scale in ASCEND MG Phase 2a trial of batoclimab in patients with MG.
  - In the ASCEND GO-2 Phase 2b trial in TED, treatment with batoclimab reduced both IgG and disease specific pathogenic IgG over the 12-week treatment period. However, the efficacy results, based on

approximately half the anticipated number of subjects who had reached the week 13 primary efficacy analysis at the time of the termination of the trial, were inconclusive.

- **Development plan and upcoming milestones:**
  - Following alignment with the regulatory authorities from the Neuro division of the FDA, and contingent on that feedback, we plan to initiate a pivotal trial in MG in the early part of calendar year 2022.
  - Contingent upon FDA feedback, we plan to re-initiate our program in TED following initiation of our MG program.
  - Contingent upon FDA feedback, we plan to re-initiate our WAIHA program following initiation of our MG program.
  - We plan to announce at least two new indications and submit INDs and our trial designs for those new indications to the FDA by August 2022.
- **Roivant ownership:**
  - As of September 30, 2021. we own 64% of the issued and outstanding shares of Immunovant common stock and 59% on a fully diluted basis.
- **Pipeline:**



Batoclimab

Batoclimab is a novel, fully human monoclonal antibody that selectively binds to and inhibits FcRn. In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce IgG antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in these disease areas.

In addition to generating clinically meaningful IgG reductions, batoclimab has been designed from inception to be a fixed-dose, self-administered SC injection on a convenient weekly, or less frequent, dosing schedule. We believe that batoclimab, if developed and approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases. The patent family directed to the composition of matter of batoclimab has a natural projected expiration date in 2035 in the U.S. and in foreign jurisdictions.

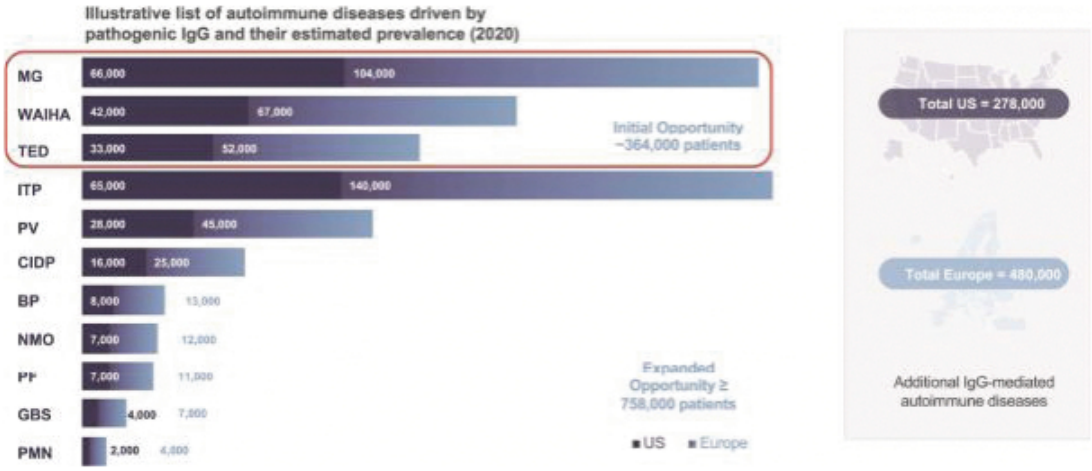
Mechanism of action

The neonatal fragment crystallizable receptor, or FcRn plays a pivotal role in preventing the degradation of IgG antibodies. The physiologic function of FcRn is to modulate the catabolism of IgG antibodies. FcRn intercepts IgG, which would otherwise be degraded in lysosomes. The FcRn-IgG complex is then recycled to the
cell surface and free IgG is released back into circulation. Anti-FcRn antibodies bind to FcRn, thereby preventing it from recycling IgG antibodies back to circulation. As a result, IgG is increasingly delivered to lysosomes for degradation. The inhibition of FcRn, such as through use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies, suggesting utility in the many autoimmune diseases associated with high levels of such IgG antibodies.

Autoimmune Diseases

Autoimmune diseases are conditions where an immune response is inappropriately directed against the body's own healthy cells and tissues. Many of these diseases are associated with high levels of pathogenic IgG antibodies, which are the most abundant type of antibody produced by the human immune system, accounting for approximately 75% of antibodies in the plasma of healthy people. IgG antibodies are important in the defense against pathogens, such as viruses and bacteria. In many autoimmune diseases, IgG antibodies inappropriately develop against normal proteins found in the body, directing the immune system to attack specific organs or organ systems.

Unfortunately, safe and effective treatment options for patients suffering from autoimmune diseases are inadequate. Currently available treatments are generally limited in early-stage disease to corticosteroids and immunosuppressants, and in later-stage disease to IVIg or plasma exchange. These approaches often fail to address patients' needs since they are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.



Europe includes all E.U. countries, the U.K. and Switzerland. MG: Myasthenia Gravis; WAIHA: Warm Autoimmune Hemolytic Anemia; TED: Thyroid Eye Disease; ITP: Idiopathic Thrombocytopenic Purpura; PV: Pemphigus Vulgaris; CIDP: Chronic Inflammatory Demyelinating Polyneuropathy; BP: Bullous Pemphigoid; NMO: Neuromyelitis Optica; PF: Pemphigus Foliaceus; GBS: Guillain-Barré Syndrome; PMN: PLA2R+ Membranous Nephropathy.

As a result of the rational design of batoclimab, we believe that batoclimab, if approved for use, could provide the following benefits:

- ***Subcutaneous delivery.*** Based on pharmacokinetics ("PK") and pharmacodynamics ("PD") and clinical data, we believe that we will be able to obtain therapeutically relevant levels of IgG reduction using 2-mL or lesser volume SC injections. The current formulation is concentrated at 170 mg/mL.

- ***Simple dosing schedule.*** We are developing batoclimab as a fixed-dose subcutaneously administered regimen without the need for preceding intravenous induction doses or lengthy SC infusions. If approved, we intend to market batoclimab as a fixed-dose pre-filled syringe or auto-injector, which would allow for convenient self-administration, eliminating the need for frequent and costly clinic visits, and reduce complexity and errors associated with calculating individual doses.
- ***Low immunogenicity risk***. Batoclimab is a fully human monoclonal antibody, and therefore contains only amino acid sequences native to humans, hypothesizing a lower risk of immunogenicity development.
- ***Low effector function.*** Batoclimab has been engineered to prevent activation of other components of the immune system, and, as a result, unintended immune response to batoclimab is not expected. Specifically, well-characterized and validated mutations introduced into the fragment crystallizable domain of batoclimab have reduced its ability to cause antibody-dependent cell-mediated cytotoxicity ("ADCC") and complement-dependent cytotoxicity ("CDC").

Recent Developments in Our Clinical Programs

In February 2021, we voluntarily paused dosing in our clinical trials for batoclimab due to elevated total cholesterol and LDL levels observed in some trial subjects treated with batoclimab. We have informed regulatory authorities and trial subjects and investigators of this voluntary pause of dosing in our studies that were ongoing at that time, ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease and ASCEND-WAIHA, a Phase 2 trial in Warm Autoimmune Hemolytic Anemia.

Program-Wide Review

In order to better characterize the observed lipid findings, we conducted from February 2021 through May 2021 a program-wide data review (including both clinical and nonclinical data) with input from external scientific and medical experts.

In our ASCEND GO-2 trial, lipid parameters were assessed at baseline, at week 12, and at week 20 following eight weeks off drug. Based on preliminary, unblinded data, median LDL cholesterol at week 12 was increased by approximately 12 mg/dL in the 255 mg dose group (corresponding to an increase from baseline of approximately 15%), by approximately 33 mg/dL in the 340 mg dose group (corresponding to an increase from baseline of approximately 37%), by approximately 62 mg/dL in the 680 mg dose group (corresponding to an increase from baseline of approximately 52%) and did not increase in the control group. The data analysis indicates a dose-dependent increase in lipids. Average high-density lipoprotein ("HDL") and triglyceride levels also increased but to a much lesser degree. We also observed correlated decreases in albumin levels and the rate and extent of albumin reductions were dose-dependent. Subjects receiving the 255 mg weekly dose ("QW") experienced the smallest reductions in albumin through week 12, with a median reduction of about 16% from baseline, while subjects receiving the 340 mg or 680 mg QW dose experienced median reductions of albumin of 26% or 40%, respectively. At week 20, both lipids and albumin returned to baseline.

In our open label ASCEND WAIHA trial, only two subjects completed 12 weeks of dosing prior to the program-wide pause in dosing, with three additional subjects partially completing the dosing period. Pre-specified and post-hoc lipid test results from these five subjects were analyzed along with post-hoc lipid test results performed on frozen samples from ASCEND MG subjects (where available) and post-hoc lipid test results from our Phase 1 Injection Site study. LDL elevations observed in the ASCEND WAIHA and ASCEND MG subject populations and in healthy subjects in the Phase 1 Injection Site Study also appeared to be dose-dependent and were generally consistent in magnitude with the elevations observed in ASCEND GO-2 subjects.

No major adverse cardiovascular events have been reported to date in batoclimab clinical trials.

Integrated Safety Assessment and Regulatory Interactions

It is our intent to resume development across multiple indications for batoclimab. We are in the process of drafting multiple study protocols and updating our program-wide safety strategy for discussions with regulatory agencies. The elements of our development program will include extensive PK and PD modeling to select dosing regimens for batoclimab which optimize reductions in total IgG levels while minimizing the impact on albumin and LDL levels, particularly for clinical studies containing long-term treatment extensions. These protocols will likely include protocol-directed guidelines for the management of any observed lipid abnormalities. While increases in LDL over a short-term treatment duration would not be expected to pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. We have initiated discussions with the FDA and expect to continue to engage with the FDA and other regulatory agencies during the second half of calendar year 2021.

Phase 1 Clinical Trials of Batoclimab in Healthy Volunteers

We have completed a multi-part, placebo-controlled Phase 1 clinical trial involving 99 healthy volunteers in Australia and Canada, administering batoclimab both as an intravenous infusion and as a SC injection. In this trial, 77 subjects received at least one dose of batoclimab and 22 subjects received placebo.

Program-Wide Data Review

Pharmacokinetics and Pharmacodynamics

The PK and PD (including serum concentrations of total IgG, albumin, and lipids) of were evaluated in healthy subjects in our Phase 1 clinical trial and Phase 1 Injection Site Study, and in patients with MG, TED and WAIHA in our ASCEND MG, ASCEND GO-1, ASCEND GO-2 and ASCEND WAIHA trials. To date, single doses of batoclimab ranged from 100 mg to 1530 mg IV and 1.5 mg/kg to 765 mg SC and were administered to healthy subjects. Multiple doses of 255 mg, 340 mg and 680 mg SC QW have been studied in healthy subjects (up to 4 weeks of dosing) and patients with TED, MG or WAIHA (up to 12 weeks of dosing).

Pharmacokinetics

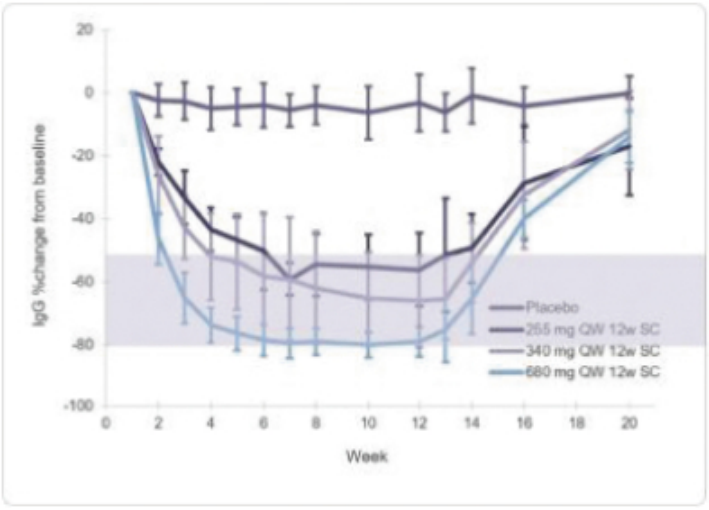
Batoclimab exhibited a non-linear PK profile which was typical of that characterized by target-mediated drug disposition (“TMDD”). The elimination of batoclimab can be divided into three phases according to the concentrations. The first phase shows linear elimination; when drug concentrations are high enough to saturate targets, drug elimination is governed by linear non-target-related routes, together with a fixed rate of target-mediated elimination, which is negligible in this phase. At the second phase, the drug concentrations become lower, the targets are not all saturated and both non-target-mediated and target-mediated elimination routes are important, resulting in nonlinear PK. At the last phase, the drug concentrations are so low that targets are not saturated, the target mediated elimination becomes the main route of elimination, and the PK becomes linear again. The drug concentrations achieved after 680 mg SC QW dose were mainly in the linear elimination phase of the PK profile, may maintain target saturation during the dosing intervals for most of the subjects. However, the drug concentrations achieved after the 340 mg or 255 mg SC QW dose may not always maintain target saturation during the dosing intervals for majority of the subjects.

Pharmacodynamics

Currently, ASCEND GO-2 in TED is the largest study (total of 65 subjects, including 18 subjects on placebo) which evaluated placebo and 3-dose levels of IMVT-1401 at 255 mg, 340 mg and 680 mg administered SC weekly for 12 weeks (“QW*12”). The preliminary PD results of total IgG by time and treatment group is presented in the below figure. The baseline serum levels of total IgG, albumin, LDL, and HDL were comparable across all treatment groups. After active treatment, the levels of total IgG and albumin started to decrease, but the levels of LDL and HDL started to increase; both the rate and extent of reductions in total IgG and albumin or

elevations of LDL and HDL were dose dependent. After 255 mg, 340 mg or 680 mg QW*12, the median Emax of total IgG reduction was 62%, 69% or 80%, respectively. For Groups 255 mg and 340 mg, total IgG levels continued to decrease as of week 12 (the last injection). For Group 680 mg, total IgG reached maximum reduction around week 7, and maintained in a plateau-like manner between weeks 7 to 12. The median Emax of albumin reduction was 16%, 26% or 40% for the 255 mg, 340 mg or 680 mg QW*12 doses, respectively. For Groups 340 mg and 680 mg, albumin levels continued to decrease as of week 12 (the last injection). For Group 255 mg, albumin reduction reached maximum around week 8, and maintained in a plateau-like manner between weeks 8 to 12. After 255 mg, 340 mg or 680 mg QW*12, the median elevation at Week 12 was 15%, 37% or 52%, respectively for LDL, and 14%, 10% or 25%, respectively for HDL. For all three active dose groups, the levels of total IgG, albumin, LDL and HDL returned to baseline within 8 weeks after the last dose of the 12-week treatment.

Mean (±SD) Percentage Change from Baseline of Serum Concentrations of Total IgG in Subjects in ASCEND GO-2 (Preliminary Results)



The relationships of the PD effects in total LDL vs. albumin indicate that the time course and extent of LDL elevations were highly correlated with albumin reductions. The reductions in both IgG and albumin were also highly correlated, with a coefficient of determination of $R^2 = 0.793$. It was also noted that the lipid elevations were not correlated with changes in thyroid hormone levels (no correlations to changes in T3, T4 or TSH were observed).

Within the dose range studied, the rate and extent of total IgG reductions, albumin reductions and lipid elevations were dose dependent across different populations and the shoulder region of the dose-response curve for total IgG reductions was covered and observed. However, the shoulder region of the dose-response curve for albumin reductions or lipid elevations was not clearly observed. The extent of PD response was much larger in reductions of total IgG than reductions of albumin or elevations of lipids.

Comprehensive understanding of the PK and PD characteristics of batoclimab has enabled creation of robust mathematical models to support the selection of future dosing regimens. The discordance between the PK/PD response relationship for IgG and that of albumin or LDL suggests options for dosing regimens that provide potentially effective reductions in total IgG (and pathologic autoantibodies) while minimizing effects on albumin and LDL levels. Optimized dosing regimens, if shown to be effective, could improve the risk/benefit profile of

batoclimab while the ease of administration of our current formulation could enhance the overall patient experience.

Safety data

We conducted, from February 2021 through May 2021, a program-wide data review, including safety data review, with input from external scientific and medical experts. The safety data review for each of the studies is described below.

In our multi-part, placebo-controlled Phase 1 clinical trial, batoclimab was observed to be generally well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs. The most commonly reported AEs were mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving batoclimab and placebo. These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. As previously disclosed, two serious AEs were reported, both of which were assessed as unrelated to batoclimab by the study investigator. There were no treatment-related serious AEs reported.

A summary of the most commonly reported AEs, defined as the AE reported occurred in more than one subject, is set forth in the table below:

Most Common Adverse Events Reported in Phase 1 Clinical Trial of Batoclimab

	Single Ascending Dose												Multiple Ascending Dose Subcutaneous Injection		
	Intravenous Infusion						Subcutaneous Injection								
Number of Subjects	0.1 MG/KG N=4	100 MG N=6	340 MG N=6	765 MG N=6	1530 MG N=6	Placebo N=8	0.5 MG/KG N=3	1.5 MG/KG N=6	5 MG/KG N=6	340 MG N=6	500 MG N=6	765 MG N=6	Placebo N=10	340 MG N=8	680 MG N=8	Placebo N=4
MedDRA Preferred Term																
Abdominal pain									1					1		
Abdominal pain upper													2	1		
Abnormal sensation in eye					1					1						
Back pain						2					1		1	1		
Constipation						1								1		
Cough											1		2			
Diarrhea														2		
Dizziness						1							1			1
Dry skin													1		1	
Erythema							1								1	
Fatigue	1			1	1	1	1			1			1			
Headache	1	1	1	1	1			1	1	4	1		1	2		
Injection site erythema									5	1	5	6	7	8	7	4
Injection site pain											1			2		1
Injection site swelling									3		2	4	3	7	6	2
Insomnia									1					4		
Myalgia														1	1	
Nasal congestion									1		1		1	1		
Nausea									1	1			1		1	1
Ocular hyperaemia															2	
Oropharyngeal pain	1			1	2				1		1		1	2		
Pain in extremity						1							1			
Procedural complication								1		1						
Procedural dizziness					2						1					
Pyrexia			1	1					1							
Rash					2				2				2		1	
Rhinorrhoea									1				2			
Sinusitis			1										1			
Somnolence		1							1							
Upper respiratory tract infection	1	1	1				3		1	1				1		
Vision blurred					1					1						

In November 2018, one serious AE (malpighian carcinoma) occurred in a 51-year-old subject who had received a single 765 mg subcutaneous administration of batoclimab. Fifty-five days after study drug administration, the subject presented to his personal physician with a left-sided neck mass. Biopsy results determined the mass to be a poorly differentiated malpighian carcinoma, which was assessed as unrelated to batoclimab by the study investigator. In February 2019, a 25-year-old subject who received a single dose 1530 mg of batoclimab by intravenous infusion presented five days later with uncomplicated acute appendicitis and the presence of an appendiceal stone. The subject underwent laparoscopic appendectomy and recovered with an uneventful post-operative course. The event was considered unrelated to study drug by the study investigator.

Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects appeared to reach nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg

cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). These reductions were not associated with any AEs or clinical symptoms and did not lead to any study discontinuations.

Our Phase 1 Injection Site study, a randomized, double-blinded, placebo-controlled, crossover study to characterize the PK, PD, safety and tolerability of batoclimab was administered as single subcutaneous doses in three different injection sites in healthy participants (N = 21). In this trial, batoclimab was generally well tolerated with no serious AEs reported and there were no discontinuations due to AEs. All AEs were assessed to be unrelated to batoclimab by the study investigator. Mild headache was reported in 33% of the overall group as compared with 25% of the placebo group.

In our ASCEND GO-1 clinical trial, where seven participants completed the treatment period of the study and five of those participants completed the follow-up, off treatment period (the two discontinuations were not related to the study), the safety and tolerability profile observed was consistent with the Phase 1 clinical trials. In this trial, no serious AEs were observed and there were no discontinuations due to AEs. Batoclimab was generally well-tolerated, with the reported AEs, ranging from mild to moderate, being increase in weight, cough, fatigue, palpitations, light-headedness, and low blood pressure. One participant had a pre-existing condition of hypertension with borderline low platelets at baseline and a low platelet count after week 18.

In our ASCEND MG clinical trial, which included five participants in the 340 mg dose group, six participants in the 680 mg dose group and six participants in the placebo group, two serious AEs were reported but determined to be unrelated to batoclimab by the study investigator.

In our ASCEND GO-2 clinical trial, five out of 18 participants in the 680 mg dose group reported peripheral edema with no such events noted in the other treatment groups. The events were Grade 1 or 2 (on a scale of 1 to 5), were limited in duration, and did not require permanent discontinuation of study drug. There were no reported cardiac events and injection site erythema was more common in the treated groups as compared with the placebo group. In the 255 mg dose group, one AE, optic neuropathy, was considered serious due to hospitalization, but was ultimately determined to be unrelated to the study and the participant later recovered. Triglycerides were elevated in the 340 mg and 680 mg dose groups with two participants reporting levels above 300 mg/dL and <400 mg/dL. No other serious AEs were reported.

The ASCEND WAIHA study is an open-label trial that has been evaluated with interim results. To date, one of the five trial subjects discontinued therapy after three 680 mg SC QW doses due to a serious AE (Immune thrombocytopenia). In January 2021, a 59-year-old subject presented for the scheduled week 4 study visit and reported gingival bleeding. The week 4 dose was not administered and laboratory results revealed decreases in platelet count. Platelet count was already at a decreased level at the time of enrollment. The subject received multiple platelet transfusions over the following few weeks. In February 2021, the AE was considered as resolved and no further transfusions were needed at that time. The study investigator considered the event related to aggravation of underlying disease activity (hemolytic anemia with immune thrombocytopenia) since the subject had decreased platelet counts at initial diagnosis; however, the study investigator stated that the investigational product's role in causing or aggravating thrombocytopenia cannot be ruled out. The adverse event was determined to be possibly related to study drug.

As previously disclosed, lipid levels were not measured contemporaneously during these Phase 1, ASCEND MG and ASCEND GO-1 clinical trials of batoclimab. See "Recent Developments in Our Clinical Programs" for further discussion about lipid and albumin changes noted in our clinical trials.

Across all the clinical trial groups to date, we believe the safety profile of batoclimab at the doses studied over a treatment interval of at least 12 weeks is acceptable and supports further development of these dosing regimens. As discussed in "*Recent Developments in Our Clinical Programs*," dose-dependent decreases in albumin levels have been observed with batoclimab; however, these decreases were generally asymptomatic

except for the potentially expected AE of peripheral edema which was observed only in the 680 mg dose group and resolved without permanent discontinuation of batoclimab. Dose-related increases in LDL and total cholesterol have also been observed with batoclimab. While increases in LDL of this magnitude over a 12-week treatment duration would not be expected to pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. Future study designs which include long-term treatment extensions will employ extensive PK/PD modeling to select dosing regimens that optimize reductions in total IgG while minimizing effects on albumin and LDL. These protocols will likely include protocol-directed guidelines for the management of any observed lipid abnormalities. The indications that we are pursuing with batoclimab are associated with substantial morbidity and currently available treatments (e.g., high dose intravenous methylprednisolone) associated with significant side effects. Therefore, we believe that, if batoclimab is found to be effective in these diseases, the safety profile observed to date should result in a favorable risk-benefit profile for batoclimab.

No major adverse cardiovascular events have been reported to date in IMVT clinical trials.

Immunogenicity Data

The development of anti-drug antibodies ("ADA") to batoclimab was assessed across all dosed cohorts following single (IV and SC formulations) and multiple (SC formulation) administrations of batoclimab. Preliminary data show a similar frequency of treatment-emergent ADA development among subjects who received at least one administration of batoclimab or placebo (8% and 6%, respectively). The antibody titers were low (£ 1:16) consistent with the high sensitivity of the ADA assay. No subjects in either the 340 mg or 680 mg multiple ascending dose cohorts developed ADAs with treatment. ADAs will continue to be monitored throughout the development program.

Batoclimab for the Treatment of Myasthenia Gravis

MG overview and limitations of current treatments

Myasthenia Gravis is a rare autoimmune disorder, characterized by weakness of muscles including ocular, head, oropharyngeal, limb and respiratory muscles. The prevalence of MG is estimated to be one in 5,000, with up to 66,000 cases expected in the United States. Existing therapies are associated with significant side effects and an unmet medical need persists. Approximately 10% of MG patients are refractory to current treatments, while up to 80% fail to achieve complete stable remission.

Very early-stage MG is symptomatically treated with acetylcholinesterase inhibitors such as pyridostigmine, which block the breakdown of acetylcholine at the neuromuscular junction, thereby increasing its concentration and capacity to activate the muscle. As the disease progresses, patients are typically treated with immunosuppressive agents such as glucocorticoids, azathioprine, mycophenolate mofetil and cyclosporine. As MG becomes more advanced, patients can be treated during exacerbations with IVIg, which provides therapeutic benefit through multiple potential mechanisms including the saturation of FcRn. However, IVIg requires recurrent, burdensome infusions to obtain significant reductions in symptoms, and the large volumes of intravenous fluid associated with the administration of IVIg can lead to significant side effects, including pulmonary edema and renal complications and treatment can be complicated by events associated with intravascular thrombosis.

Physicians direct patients with more advanced chronic disease and patients in times of crisis to therapies that reduce levels of circulating IgG antibodies. One method of reducing IgG levels is to take blood from a patient and physically remove the patient's plasma before returning the red blood cells as well as outside obtained albumin or plasma to the patient in a process called plasma exchange. This is a slow process that typically takes several hours and often requires multiple treatment sequences due to limited daily tolerance (a reported mean of 6 treatments in MG) over a number of days in order to achieve a significant reduction in IgG antibody levels. A

variant of this procedure is immunoadsorption in which bacterial proteins are used to selectively remove IgG antibodies from serum. The most recent agent approved for MG is eculizumab, a complement C5 inhibitor, the use of which is limited to patients refractory to available therapy with anti-AChR-positive MG. Anti-MuSK antibodies have a low propensity to activate complement proteins, thus C5 inhibition may not be therapeutically relevant in anti-MuSK-positive patients. Studies indicate that patients with MuSK-positive disease are more likely to become treatment refractory thus presenting an additional unmet need.

Development plan

Before the voluntary pause of dosing, we had a favorable end of Phase 2 meeting with the FDA on the design of our Phase 3 registrational program in MG and we are planning on advancing our clinical trials for this indication. Based on our integrated safety analysis, we plan to meet with the FDA to propose further development to evaluate additional dosing levels and regimens as well as to include additional safety monitoring and considerations such as lipid and albumin monitoring and incorporating an independent safety monitoring committee. Contingent upon FDA feedback, we plan to initiate a pivotal study in MG in the early part of calendar year 2022.

Batoclimab for the Treatment of Warm Autoimmune Hemolytic Anemia

WAIHA overview and limitations of current treatments

WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of RBCs. The clinical presentation is variable and most commonly includes non-specific symptoms of anemia such as fatigue, weakness, skin paleness and shortness of breath. Symptoms typically develop chronically over several weeks to months, however, rapid progression over a span of days has also been observed. In severe cases, hemoglobin levels are unable to meet the body's oxygen demand, which can lead to heart attacks, heart failure and even death. Though the exact causes of WAIHA are unknown, roughly half of cases occur in patients with an underlying lymphoproliferative or autoimmune disease, most commonly chronic lymphocytic leukemia, rheumatoid arthritis or systemic lupus erythematosus.

In WAIHA, autoantibodies react with surface proteins on RBCs at temperatures at or above 37 degrees Celsius, or normal body temperature. These antibodies are of the IgG subtype in the majority of patients. WAIHA is differentiated from cold autoimmune hemolytic anemia, or cold agglutinin disease, which shares a similar clinical presentation but is triggered by autoantibodies that react at temperatures below 37 degrees Celsius. In WAIHA, antibody-coated RBCs are removed from circulation primarily in the spleen, where they are destroyed by macrophages. Studies have suggested the severity of WAIHA correlates with the amount and potency of autoantibodies present. The laboratory evaluation of WAIHA begins with a peripheral blood analysis revealing evidence of extravascular hemolysis (spherocytes, low haptoglobin, elevated bilirubin and elevated LDH). In over 97% of cases, patients have a positive direct antiglobulin test, which detects the presence of IgG or complement proteins bound to the surface of RBCs.

The annual incidence of WAIHA in the United States and Europe is estimated at one to three in 100,000 persons. Based on published estimates, we believe that there are approximately 42,000 patients in the United States and 67,000 patients in Europe living with WAIHA. The disease may be more common in females, with some sources suggesting a 2:1 female predominance. Peak incidence occurs during the sixth and seventh decades of life, however, WAIHA can occur in children as well.

High doses of corticosteroids (>1 mg/kg of prednisone) are typically the first-line treatment option for WAIHA and lead to initial disease control in approximately 70-85% of cases. Once initial disease control is achieved, doses of steroids are tapered. However, only 33% of patients maintain sustained disease control once steroids are discontinued and, as a result, the majority of patients will require either long-term steroid treatment or additional therapies.

There are few studies to guide which treatment options to use in patients failing corticosteroids. Until recently, splenectomy had been a common second-line treatment option for patients not responding adequately to corticosteroids. The therapeutic benefit of splenectomy is thought to be twofold: first, it eliminates the major site of RBC destruction in WAIHA; second, removal of the spleen reduces the total lymphoid tissue capable of producing autoantibodies. However, because of the lack of reliable predictors of the outcome, morbidity and potential operative complications of splenectomy, rituximab has become the default second-line option despite not being approved for use in WAIHA. In case studies looking at patients with relapsed disease after treatment with steroids, single-agent rituximab led to responses in 65% to 90% of patients. In such a course of treatment, maximal therapeutic effect is not immediate.

Patients with persistent disease despite use of corticosteroids and rituximab may be offered a course of other immunosuppressive drugs, such as cyclophosphamide, mycophenolate mofetil or azathioprine sirolimus. IVIg is not routinely used alone for the treatment of WAIHA, however, small case series have suggested some evidence for a therapeutic effect in patients suffering from life-threatening complications of the disease. In these reports, IVIg has been given at high doses (greater than or equal to 1 g/kg per day), and the results have been inconsistent, requiring repeated courses of treatment in at least one case. RBC transfusions are indicated in patients who require immediate stabilization. Such patients are monitored closely for evidence of a transfusion reaction. In contrast to other treatment modalities that lead to nonspecific suppression of the immune system, batoclimab may offer a more targeted approach for reducing levels of the causative IgG species responsible for most cases of WAIHA. We believe this could provide a favorable therapeutic window and avoid the significant side effects associated with less targeted immunosuppression.

Development plan

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. Prior to the clinical pause, the ASCEND WAIHA trial explored the potential of batoclimab to increase hemoglobin levels and assess the safety and tolerability of batoclimab in this population. Subjects in this trial were treated with one of two doses of batoclimab (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as subjects achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses.

For our open lable trial, ASCEN WAIHA, we plan to initiate discussions with the FDA following alignment on our MG program and, based on a favorable outcome from these meetings, we anticipate re-initiating our WAIHA program after re-initiating our MG program.

Batoclimab for the Treatment of Thyroid Eye Disease

TED overview and limitations of current treatments

TED is an autoimmune inflammatory disorder that affects the muscles and other tissues around the eyes and can ultimately be sight-threatening. TED has an estimated annual incidence of 16 in 100,000 women and 2.9 in 100,000 men in North America and Europe. The natural history of TED begins with an inflammatory phase lasting between six and 24 months. Treatment of patients with immunosuppressive therapies during this active inflammatory phase can lead to reduction in symptoms and can alter the course of the disease. However, once the initial inflammatory phase is over, immunosuppressive therapies are ineffective and levels of fibrosis that have developed as the result of acute inflammation are only reversible by surgery. We estimate that 15,000 to 20,000 patients in the United States have active inflammatory TED and are eligible for treatment. There are few treatment options currently available for TED patients. As a first option, patients with active TED are treated with immunosuppressive therapy such as high doses of corticosteroids, typically administered intravenously or

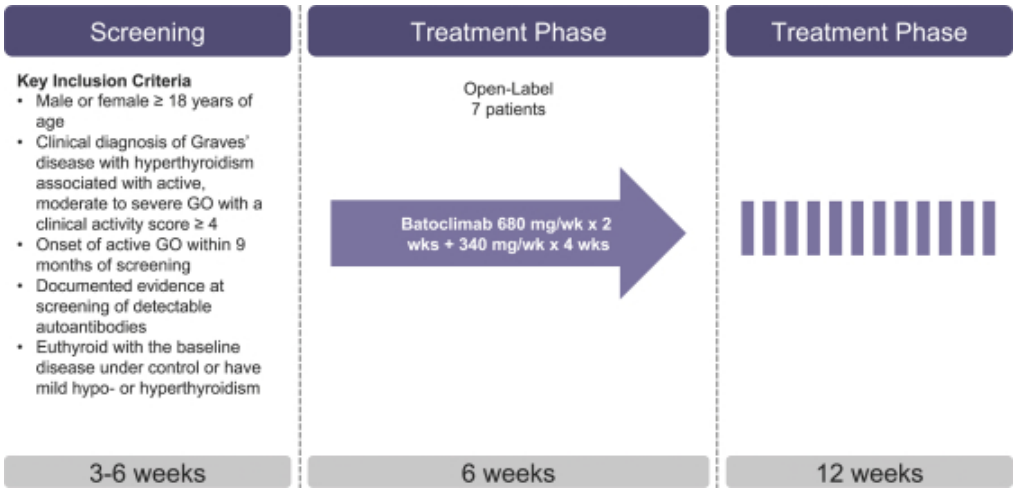
orally. Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse. This therapy is associated with an increased risk of acute and severe organ damage, bone thinning, weight gain, diabetes, hypertension, osteoporosis and depression. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED. Orbital radiation therapy may reduce the infiltration of lymphocytes and can be used in conjunction with corticosteroids or immunosuppressive therapy. Similar to these anti-inflammatory and immunosuppressive drugs, radiation therapy is most effective in the active stage of TED. Patients with moderate-to-severe active TED which is still in the active stage and who do not respond adequately to corticosteroids can be treated with cyclosporine or mycophenolate mofetil, two broad immunosuppressive drugs. These powerful drugs are associated with numerous general immunosuppressive side effects as well as inherent toxicities, such as hypertension, kidney disease, and gastrointestinal toxicity. Small case studies have identified Roche's Rituxan (rituximab) as an alternate way of inducing immunosuppression in patients with TED. However, rituximab is associated with the potential for serious side effects, such as infusion-related reactions. Surgery is considered to be a treatment option in patients with a high Clinical Activity Score ("CAS"), a measure of disease activity in TED patients, who have been treated with corticosteroids or immunosuppressive therapy but continue to have progressive disease. The goal of surgery is to reduce the pressure causing proptosis, reduced eye movement and loss of visual acuity. Due to its invasive nature, surgery is typically reserved for inactive disease.

We believe that a therapy for TED focused on addressing the cause of the disease, namely the presence of autoimmune antibodies, represents an attractive approach that has the potential to avoid many of the serious side effects of current therapies. Because the mode of action of batoclimab is independent of the antigen recognized by the autoimmune antibodies, we believe that batoclimab can address TED that arises through any IgG autoantibody mechanism whether it be anti-TSHR, anti-IGF1R, or any other IgG autoantibodies.

Clinical data

In March 2020, we announced initial results from our ASCEND GO-1 trial, an open label single-arm Phase 2a clinical trial of batoclimab in Canada in patients with TED. Subjects recruited for this trial have moderate-to-severe active TED with confirmed autoantibodies to TSHR. A total of seven subjects were dosed weekly with SC injections for six weeks. Subjects received a 680 mg dose for the first two administrations of the study followed by a 340 mg dose for the final four administrations. The primary endpoints of this trial were safety and tolerability of batoclimab over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses. Secondary clinical endpoints included mean changes in proptosis, or protrusion of the eyeball, the proptosis responder rate, defined as the percentage of subjects with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, PK and anti-drug antibodies.

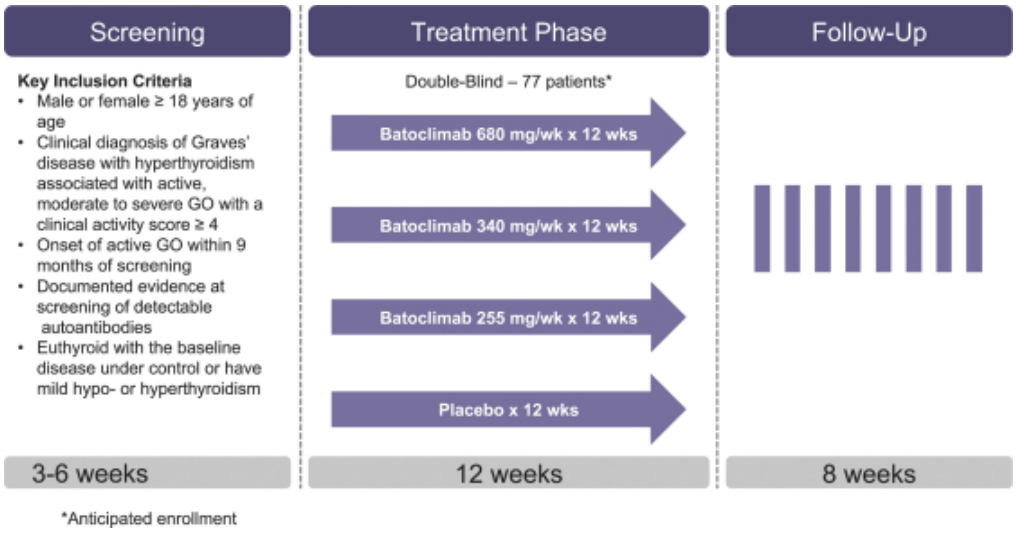
Trial Design of ASCEND GO-1 Trial



All seven subjects completed the six-week treatment phase of the trial and entered the 12-week follow-up phase. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, four of seven subjects (57%) improved by ³2 points on the CAS. Of six subjects with baseline diplopia, four subjects (67%) demonstrated improvement in diplopia. Three of seven subjects (43%) were proptosis responders. The safety and tolerability profile observed was consistent with the prior Phase 1 trial of batoclimab in 99 healthy volunteers; as previously disclosed, lipid levels were not measured contemporaneously during the Phase 1 and ASCEND GO-1 Phase 2a clinical trials of batoclimab. Mean albumin reduction from baseline to end of treatment was 24%. All AEs were mild or moderate and there were no headaches reported.

In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 subjects with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explored the potential of batoclimab to improve proptosis and assesses the safety and tolerability of batoclimab in this population. Subjects in this trial were treated with one of three doses of batoclimab (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial were the proptosis responder rate measured at week 13, defined as the percentage of subjects with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability. Secondary endpoints included the proptosis responder rate measured at weeks 2, 3, 4, 5, 6, 8, 10, 12, 14, 16 and 20, the proportion of subjects with a CAS of 0 or 1, the mean change from baseline in proptosis, CAS, diplopia, ophthalmic improvement and GO-QOL and PK, PD, defined as anti-TSHR antibodies and total IgG and IgG antibodies by subclasses, and anti-drug antibodies. Exploratory endpoints included assessment of CT-measured muscle volume, fat volume, total orbital volume and proptosis, as well as multiple biomarkers including gene expression profiles, pro-inflammatory markers and receptor occupancy.

Trial Design of ASCEND GO-2 Trial



Our voluntary pause in dosing resulted in unblinding the ASCEND GO-2 trial. As a result, following the last patient last visit of the post-treatment follow-up period, the ASCEND GO-2 trial was terminated. Treatment with batoclimab reduced both IgG and disease specific pathogenic IgG over the 12-week treatment period. However, the efficacy results, based on approximately half the anticipated number of subjects who had reached the week 13 primary efficacy analysis at the time of the termination of the trial, were inconclusive. The primary endpoint of the proportion of proptosis responders was not met, and although not tested statistically, post hoc evaluation of other endpoints measured (CAS and diplopia scores) indicated the desired magnitude of treatment effect likely would not have been achieved. However, levels of IgG were reduced across batoclimab dosing groups, and analysis of the receptor occupancy data suggest binding of batoclimab to the Fc receptor.

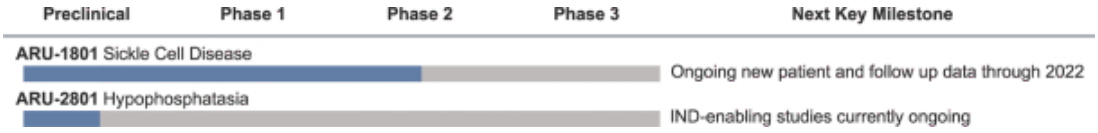
Development plan

For TED, efficacy results based on the data at the time of pausing our ASCEND GO-2 trial were inconclusive. We intend to initiate discussions with regulatory authorities following alignment on our MG program and re-initiate our program in TED after re-initiating our MG program.

Aruvant Overview

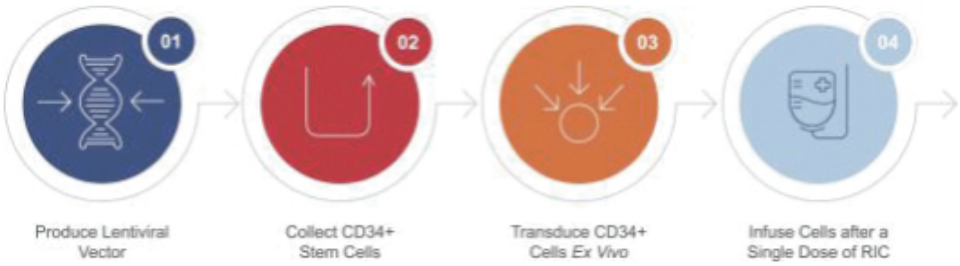
- **Overview:**
  - Aruvant is developing ARU-1801 as a one-time, potentially curative gene therapy for the treatment of sickle cell disease ("SCD"), as well ARU-2801, a gene therapy designed to deliver potentially curative efficacy without the limitations of chronic administration for patients with hypophosphatasia ("HPP").
- **Lead program:**
  - ARU-1801 is an *ex vivo* lentiviral gene therapy that contains a proprietary gamma-globin gene for a novel, highly potent variant of fetal hemoglobin ("HbF") and has been observed in preliminary clinical studies to engraft with only reduced intensity conditioning ("RIC").
- **Disease overview:**
  - SCD results from a defect in the gene that encodes beta-globin, a component of hemoglobin, the protein that carries oxygen in the blood.
  - The abnormal sickle beta-globin can cause red blood cells to sickle, leading to obstruction of small blood vessels, resulting in pain crises, progressive damage to bones, joints and major organs, and mortality in the mid-40s.
  - SCD is predominantly concentrated among individuals of African, Middle Eastern, South American and South Asian descent.
  - An estimated 100,000 people in the U.S. and 125,000 people in the E.U. suffer from SCD, with approximately 100,000 of these patients experiencing severe disease.
- **Limitations of current treatments:**
  - Common treatment for patients with SCD is the oral cytotoxic agent hydroxyurea which is required to be taken daily.
  - For patients experiencing a vaso-occlusive episode ("VOE"), only palliative therapy is currently available; treatment typically consists of hydration, oxygenation and analgesia for pain often requiring oral or intervenous opioids.
  - One potentially curative treatment available for patients with sickle cell disease is allogeneic hematopoietic stem cell transplant, in which a patient's own bone marrow is replaced by that of a healthy donor. According to an analysis of data from the National Marrow Donor Program, fewer than 15% of sickle cell patients have a sibling matched donor. Additionally, allogeneic transplant comes with the risk of graft rejection and graft versus host disease.
  - Other gene therapies are in development as a potential cure; however, unlike ARU-1801, they require the use of myeloablative chemotherapy.
- **Clinical data:**
  - All study participants for whom sufficient follow-up has been completed have realized clinically meaningful reductions in disease burden, as seen with significant reductions in hospitalized VOEs and total VOEs.
  - These participants have experienced durable engraftment and improvement in SCD burden without the use of myeloablative chemotherapy. The two patients who have received product manufactured with an updated process have experienced complete resolution of VOEs out to 18- and 12-months post-treatment.

- **Development plan and upcoming milestones:**
  - We are currently conducting the MOMENTUM Phase 1/2 study of ARU-1801 in patients with severe sickle cell disease.
  - We expect to initiate a pivotal trial in the first half of calendar year 2023.
- **Roivant ownership:**
  - As of September 30, 2021, we own 88% of the issued and outstanding Common Shares of Aruvant and 79% on a fully diluted basis.
- **Pipeline:**

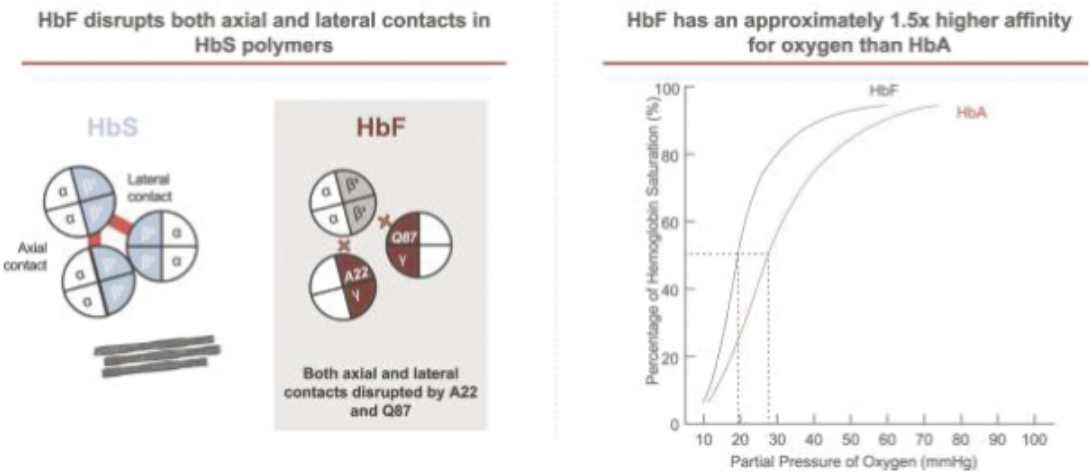


ARU-1801

ARU-1801 is an *ex vivo* gene therapy with the ability to engraft with only reduced intensity conditioning ("RIC"). ARU-1801 uses a self-inactivating lentiviral vector that contains a proprietary gamma-globin gene for a novel, highly potent variant of fetal hemoglobin ("HbF"): HbF^{G16D}.



HbF is a more potent anti-sickling globin compared to adult hemoglobin ("HbA"). HbF has mechanistic and clinical benefits observed in SCD, which makes it suitable for the treatment of SCD. HbF disrupts both axial and lateral contacts that cause polymerization of sickle hemoglobin ("HbS") polymers, and has an approximately 1.5 times higher affinity for oxygen than HbA.



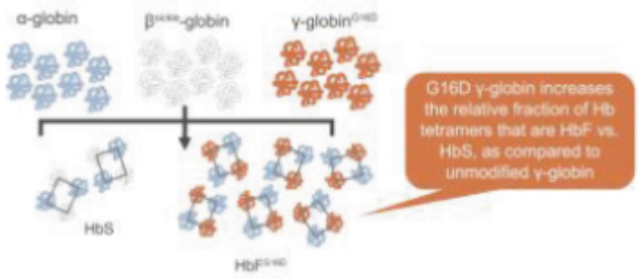
The clinical benefits of increasing HbF have been well-described in scientific literature. HbF levels greater than 8.6% improve survival by approximately 16 years in patients with SCD. HbF levels greater than 20% reduce hospitalizations by two to four-fold for vaso-occlusive events and acute chest syndrome. Further, HbF levels greater than 30% result in asymptomatic disease and patients do not develop sickle cell complications, as demonstrated in patients with SCD who also inherit Hereditary Persistence of Fetal Hemoglobin.

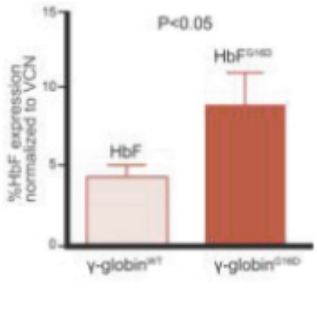
ARU-1801 originated in the laboratory of Punam Malik, MD, director of the Cincinnati Comprehensive Sickle Cell Center at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). Dr. Malik previously served as the director of the Cincinnati Children's Translational Core Services, which developed and manufactured viral vectors for multiple clinical trials. A leading expert in lentiviral gene therapy, stem cell biology and clinical care of hemoglobinopathies, Dr. Malik remains a key scientific advisor to Aruvant.

Potential benefits of ARU-1801

There are several unique attributes of ARU-1801 that we believe enable the use of reduced intensity conditioning for engraftment, and potential clinical efficacy at lower vector copy number ("VCN").

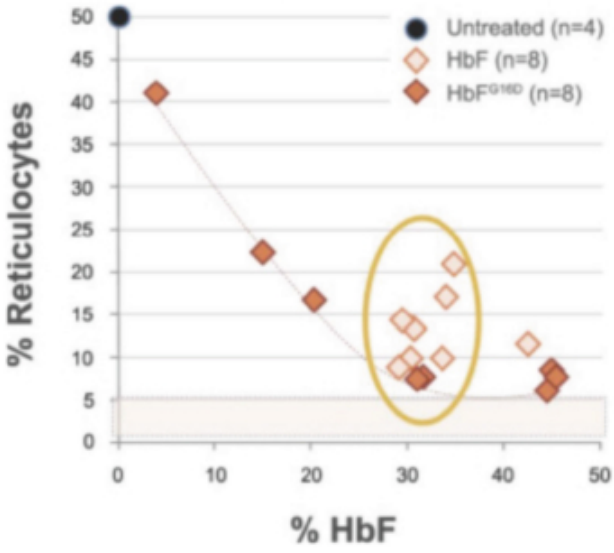
- ***Proprietary G16D modification drives higher HbF payload per vector copy.*** A proprietary G16D point mutation that changes glycine (G) at position 16 to aspartic acid (D) drives higher HbF payload per vector copy. Gamme-globin^{G16D} has a higher affinity for alpha-globin and is thus more likely to form HbF, as compared to unmodified gamma-globin. In well-established SCD mouse models, vector encoding gamma-globin^{G16D} led to 1.5x to 2x more HbF per vector than vector encoding unmodified gamma-globin.



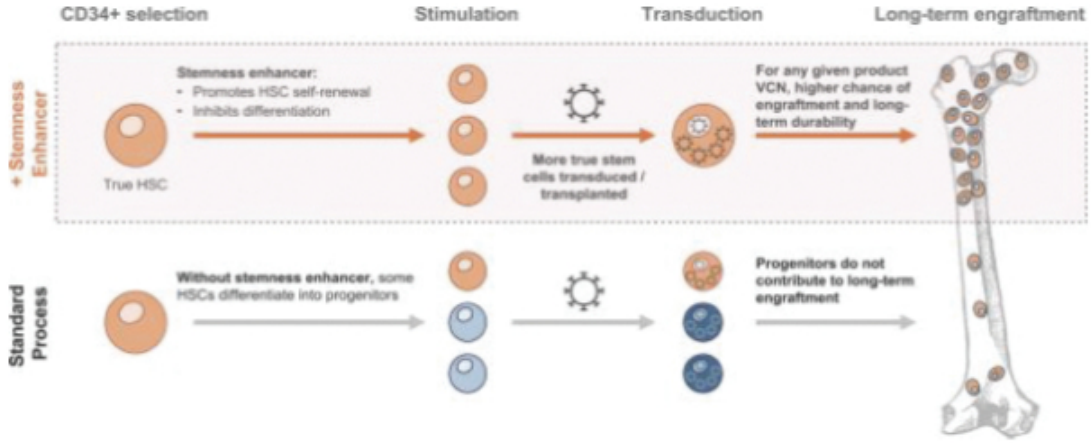


- ***High HbF^{G16D} payload may have a more potent clinical anti-sickling effect than endogenous HbF.*** HbF^{G16D} may have a more potent anti-sickling effect than endogenous HbF. In preclinical studies, a lower percentage of reticulocytes indicates less sickling and hemolysis. At the percentage of HbF highlighted below, HbF^{G16D} is superior to endogenous HbF at reducing reticulocyte count.

Hemolysis in SCD mice



- ***Our proprietary stemness enhancer facilitates engraftment.*** Our cellular manufacturing process leverages a proprietary stemness enhancer to facilitate the transduction and engraftment of more true stem cells. Stemness enhancers allow for a higher chance of engraftment for a given VCN compared to engraftment without a stemness enhancer, as illustrated below.



- ***Ability to engraft using only reduced intensity conditioning***. In preliminary clinical studies, ARU-1801 demonstrated engraftment and the ability to deliver potentially curative treatment without fully myeloablative chemotherapy.

  We believe that the RIC regimen used for ARU-1801, melphalan 140mg/m^2, may provide significant clinical benefits compared to the higher intensity myeloablative busulfan-based regimen used by the other investigational SCD gene therapy candidates, including:

  - reduced duration of neutropenia and thrombocytopenia;
  - potential for outpatient administration, which would significantly reduce resource utilization in the health care setting;
    - reduced intensity conditioning with melphalan for autologous transplants has required a median hospital stay between 0-5 days within 30 days of infusion, which represents a significant improvement in both patient experience and reduction in health care cost compared to myeloablative conditioning regimens that require a median hospital stay of 44 days; and
  - reduced likelihood to result in infertility, with a risk of ovarian failure around 30-40% compared to 70-80% with myeloablative regimens.

  High intensity fully myeloablative conditioning regimens have been associated with increased risk of malignancy. The reduced intensity melphalan-based conditioning regimens for autologous transplants in the setting of multiple myeloma have been associated with a 0.2% risk of AML and a 1-1.4% combined risk of AML and other secondary hematologic malignancies.

ARU-1801 with reduced intensity conditioning (melphalan 140mg/m2) has the potential to provide benefit to patients, providers and payors

Note: no head-to-head studies of these products have been conducted

	Busulfan 3.2 mg/kg/day* (Used by myeloablative gene therapies)	Melphalan 140 mg/m² (Used by ARU-1801)
Neutropenia Recovery Time	20 days[1]	7 days[2]
Platelet Recovery Time	28 days[1]	8 days[2]
Neurotoxicity	Seizure prophylaxis required[3]	No seizure prophylaxis required[4]
Ovarian Failure	70 - 80%[5]	30 - 40%[5]
Chemo Administration	4 days[6] daily PK monitoring	1-hour infusion[4]
Days in Hospital (Median)	44 days[6]	0-5 days[7]
Potential for Outpatient Administration	Low[3] *(longer cytopenias, multiple infusions)*	High[7] *(common in multiple myeloma)*
Backup Collection	Required[8]	Not required[8]
Risk if No Engraftment	Rescue transplant required[8]	No rescue required[9]

Table reflects combination of gene therapy protocols, reported results from gene therapy trials, and literature on the use of these conditioning agents in other settings.

* Dose adjusted to a targeted AUC for busulfan of 4200 µM*min. 1. bluebird bio ASGCT 2020. Resolution of Sickle Cell Disease (SCD) Manifestations in Patients Treated with LentiGlobin Gene Therapy: Updated Results of Phase 1/2 HGB-206 Group C Study. 2. Based on data from 3 ARU-1801 patients. 3. Busulfan label; seizure prophylaxis required but not with phenytoin due to PK interaction with busulfan. 4. ALKERAN label. 5. Estimated based on Kaplan-Meier plot in post-pubescent female children based on time to elevated FSH level with up to 8 years follow up (Panasuik et al. BJH 2015). 6. ZYNTEGLO EPAR. 7. Boston Medical Center. B Freeman et al. (2014) Bone Marrow Transplantation and Guru Murthy GS et al. (2019) Biol. Blood Marrow Transplant; outpatient autologous HSCT are already performed for multiple myeloma and AL amyloidosis 8. Rescue cell collection required per bluebird bio protocol. 9. Based on Aruvant protocol.

ARU-1801 for the Treatment of SCD

Sickle cell disease and limitations of current treatments

SCD results from a defect in the gene that encodes beta-globin, a component of hemoglobin, the protein that carries oxygen in the blood. A proportion of sickled cells rising relative to non-sickled cells can obstruct small blood vessels and reduce blood flow to bones, joints and major organs. This obstruction can cause intense pain and lasting tissue damage. Patients can suffer additional complications such as stroke and frequent infections because of inadequate oxygen delivery to the brain and spleen. Over time repeated tissue damage leads to a loss of vital organ function and a vastly reduced life expectancy; mean age of death in the US for patients with SCD is 44 years. SCD is predominantly concentrated among individuals of African, Middle Eastern, South American
and South Asian descent. An estimated 100,000 people in the U.S. and 125,000 people in the E.U. suffer from SCD, with approximately 100,000 patients experiencing severe disease. Market research based on a survey of over 100 physicians conducted in 2020 suggests that use of busulfan conditioning is a major barrier to adoption, restricting patient groups eligible or willing to receive treatment. The same survey of physicians suggests that of the patients with severe SCD, they would consider 49% eligible for myeloablative gene therapy, versus 70% that they would consider eligible for gene therapy with a reduced intensity conditioning regimen.

The oral cytotoxic agent hydroxyurea is a mainstay in the overall management of individuals with SCD since it reduces the incidence of VOEs, decreases hospitalization rates, and prolongs survival. However, its use is significantly limited by its side effect profile, variable patient response and long-term toxicity. For patients experiencing VOEs, only palliative therapy is currently available; treatment typically consists of hydration, oxygenation and analgesia for pain, usually using intravenous or oral opioids.

In November 2019, the FDA approved ADAKVEO to reduce the frequency of VOEs in adults and pediatric patients aged 16 years and older with SCD. In November 2019, the FDA also approved Oxbryta for the treatment

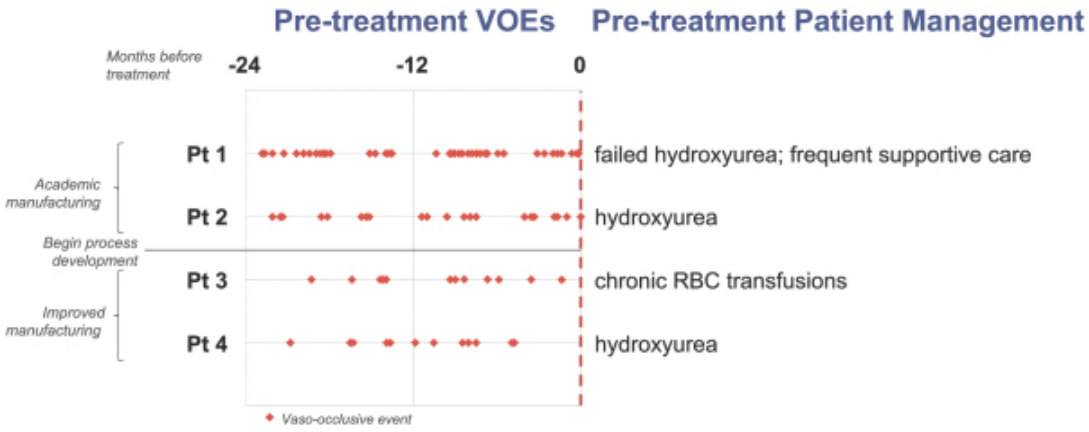
of SCD in adults and pediatric patients aged 12 years and older. Oxbryta is a once-daily oral therapy that inhibits sickle hemoglobin polymerization.

One curative treatment available for some patients with SCD is allogeneic hematopoietic stem cell transplant ("HSCT"), in which a patient's own bone marrow is replaced by that of a healthy donor. However, it requires identification of a suitable donor and carries significant morbidity and mortality risks, including an approximately 7% mortality rate. Ideal sibling matches are only available to approximately 14% of patients. Furthermore, according to the Center for International Blood and Marrow Transplant Research, only 737 HSCTs were performed for the treatment of SCD in the U.S. between 2013 and 2017, highlighting the need to bring alternative curative therapies to the remainder of the estimated 100,000 patients in the U.S. as well as the millions of patients worldwide.

Clinical data

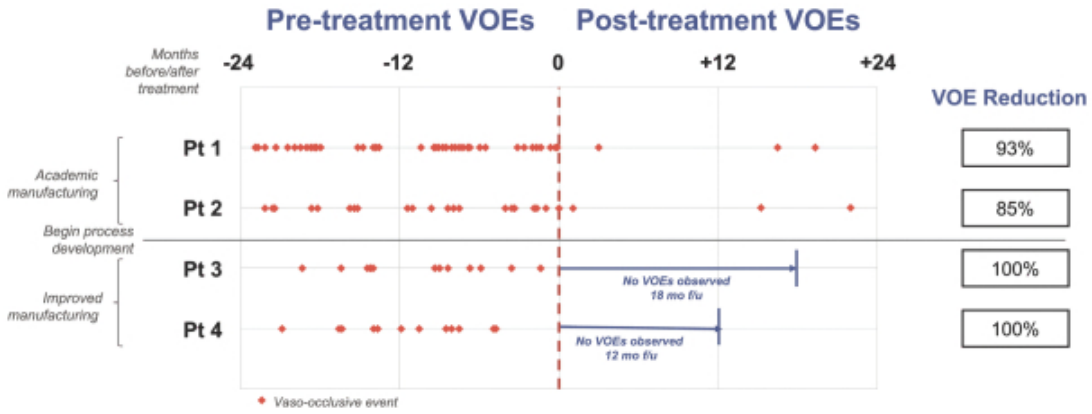
We are currently conducting the MOMENTUM Phase 1/2 study of ARU-1801 in patients with severe SCD. Eligible patients include those between the age of 18 and 45 that have failed hydroxyurea and are not candidates for allogeneic transplant. After enrollment, patients are transfused to reduce HbS below 30%, stem cells are collected, and patients receive RIC consisting of a single dose of melphalan 140 mg/m2. ARU-1801 is manufactured in a two-day period and administered via intravenous infusion.

Prior to treating the patients, we looked at the number of VOEs each participant had for the two years prior. The chart below shows that all patients had significant numbers of VOEs before receiving ARU-1801 and while being treated with the standard of care therapies.



The first two patients were treated before Aruvant licensed the product and updated ARU-1801's manufacturing process. We made, and continue to make, major investments in continuously improving our manufacturing process. Patients three and four have received product manufactured with an updated process. The first two patients have had a 93 and 85 percent reduction in their VOEs in the two years post-treatment. The more recently treated patients have seen a 100 percent reduction in their VOEs. Patient three is 18 months from treatment and patient four is 12 months from being treated. Below are the results from all four patients.

Treatment with ARU-1801 has resulted in a clinically significant reduction in VOEs



ARU-1801 was generally well tolerated, with no ARU-1801 or chemotherapy related serious adverse events reported to date. Serial analysis of vector insertion has shown polyclonal engraftment with no evidence of clonal expansion in any patients.

Adverse Events

	Patient 1	Patient 2	Patient 3	Patient 4
ARU-1801 Related				
Infusion AEs	None	None	None	None
Late AEs	None to date (36 mos)	None to date (36 mos)	None to date (18 mos)	None to date (12 mos)
Vector insertion	Polyclonal engraftment with no evidence of clonal expansion			
Chemotherapy related				
Serious	None	None	None	None
Non-serious	Cytopenias, mucositis, nausea, vomiting, cellulitis, elevated RFT and LFTs, alopecia	Cytopenias, mucositis, c-line infection, elevated LFTs	Cytopenias, mucositis, nausea, vomiting, febrile neutropenia, alopecia	Cytopenias, mouth pain, diarrhea, nausea, fatigue, elevated LFTs

Development plan

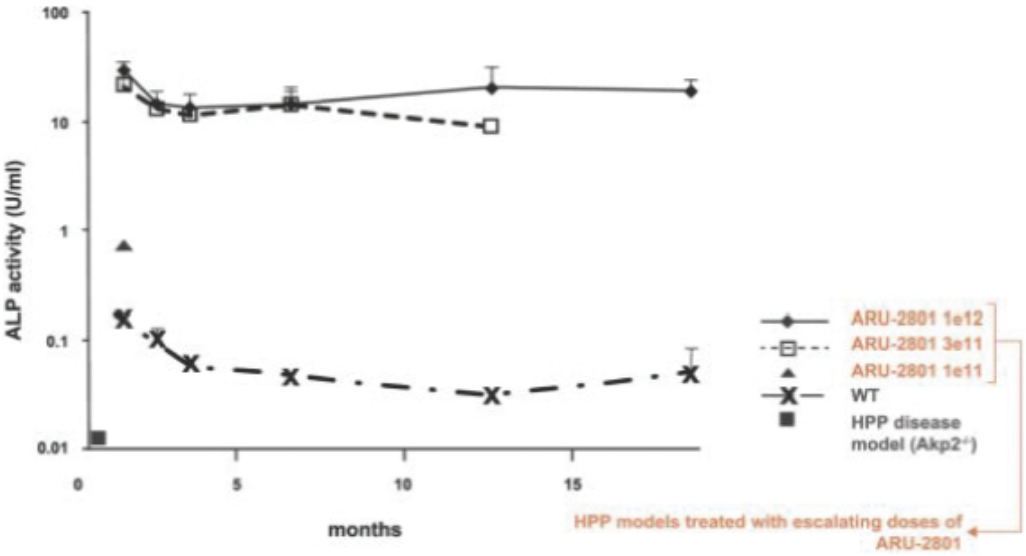
We are continuing to screen additional patients who may be eligible for ARU-1801 and gathering follow-up data on our patients dosed to date. We also continue to evolve our manufacturing process in preparation for our pivotal trial of ARU-1801 in SCD, which we expect to initiate in the first half of calendar year 2023.

ARU-2801 for Hypophosphatasia

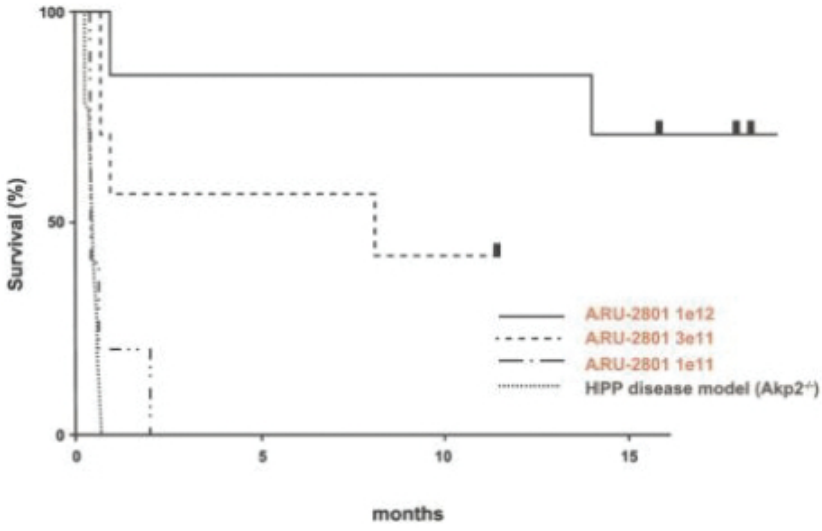
We are also developing ARU-2801, a preclinical adeno-associated virus (“AAV”) gene therapy designed to deliver potentially curative efficacy without the limitations of chronic administration for patients with HPP. This devastating, ultra-orphan disorder can result in multi-organ damage and high mortality when left untreated. HPP is caused by mutations in the gene encoding the tissue non-specific alkaline phosphatase (“TNAP”) enzyme and is wide-ranging in severity. This genetic and chronic disease is most often characterized by limited hydroxyapatite formation resulting in limited bone mineralization that can lead to destruction and deformity of bones, profound muscle weakness, seizures, respiratory failure and premature death. There are five types of HPP, including perinatal, infantile, childhood, adult and odontohypophosphatasia. There is currently an approved chronic therapy available for perinatal, infantile and juvenile-onset HPP, the enzyme replacement therapy Strensiq (asfotase alfa). Chronic administration, injection site reactions, and poor durability of Strensiq leave high unmet need that we believe ARU-2801 could potentially address.

Preclinical research shows that treatment of HPP disease model mice with ARU-2801 results in sustained elevation of TNAP at levels that ameliorated disease symptoms. In a murine model of HPP, ARU-2801 resulted in durable, high levels of ALP and survival to 18 months, as shown below. There was no evidence of ectopic calcifications at these therapeutic doses.

High ALP levels in HPP murine model (Akp2-/-)



Durable 18-month OS of 70% in HPP murine model (Akp2-/-)



Investigational new drug application-enabling studies are currently underway.

Proteovant Overview

Selected Pipeline Programs

Proteovant is enhancing its pipeline with degraders to new targets and novel E3 ligase discovery work through the capabilities described below. As of September 30, 2021, we own 60% of the issued and outstanding Common Shares of Proteovant and 60% on a fully diluted basis.

Protein degraders

Protein degraders are a novel class of small molecules that target and destroy cellular proteins, rather than inhibiting them. Degraders are small molecules engineered to induce the degradation of specific disease-causing proteins through the ubiquitin-proteasome system ("UPS"), which ordinarily tags and degrades proteins that have been misfolded or have already fulfilled their biological function. In heterobifunctional degraders, the protein ligand domain, commonly referred to as a "warhead," targets the specific protein of interest. At the other end of the complex, the ligase ligand recruits a specific E3 ubiquitin ligase. Both ends of the complex are connected by a linker that orients the target protein and E3 ligase in a cooperative ternary complex, driving ubiquitination. Similar to heterobifunctional degraders, molecular-glue-type degraders are small molecules that induce a novel interaction between a substrate receptor of an E3 ubiquitin ligase and a target protein leading to proteolysis of the target via UPS.

We believe degraders represent a promising new approach to drug previously "undruggable" targets and transform the treatment of diseases with significant unmet medical need. Degraders open a new set of opportunities for small molecule drug development, with multiple distinct potential advantages over inhibitors:

- Not bound by "active site" requirements, allowing degraders to target historically "undruggable" proteins, including transcription factors and scaffolding proteins that lack a catalytic pocket
- Achieve efficacy at lower doses to decrease dose-limiting toxicities (which have similar but not identical function to the target protein)
- Efficacy in tumors that are resistant to inhibitors, as a function of protein depletion

Our degrader strategy

We believe we are positioned for leadership in the field of targeted protein degradation given our long-term partnership with a leading academic lab, our internal R&D capabilities that span all aspects of early drug development including medicinal chemistry, biology and structural biology and chemistry, our degrader-specific ML capabilities, and our well-established clinical development capabilities.

We have access to leading medicinal chemistry capabilities via our long-term partnership with the lab of Dr. Shaomeng Wang, a world-renowned scientist focused on the discovery of protein degraders, at the University of Michigan. Over 15 years, Dr. Wang and his team have developed an initial pipeline of degraders for over 10

targets and have over 50 U.S. patents and hundreds of international patents related to degrader technology. Through our acquisition of Oncopia Therapeutics, which was co-founded by Dr. Wang, we obtained Oncopia's
pipeline, ongoing work on new targets, broad patent estate and deep knowledge and experience in the degrader space.

We expect to initiate a Phase 1 trial for our first degrader candidate in 2022 and rapidly build upon the early pipeline of degraders.

Our medicinal chemistry and degrader biology expertise are complemented by our degrader-specific ML capabilities. Proteovant has an exclusive partnership with VantAI, which, through its focus on the *in silico* design and optimization of targeted protein degraders, has developed a number of powerful and distinctive tools, including:

- A novel protein contact-first workflow that utilizes information about known protein-protein interactions to build new degraders that can effectively stabilize target-E3 interfaces
- A degron knowledge graph, which we believe to be industry-leading, that maps the ubiquitin proteasome system and enables the analysis of interactions between E3 ligases and degrons, the protein components that bind to E3 ligases and regulate degradation
- A unique model for predicting degradation based on millions of carefully curated protein stability datapoints

These techniques may enable quick and effective generation of degrader candidates and facilitate drugging targets with little or no structural information and recruiting novel E3 ligases with no known ligands. We believe that degrader drug development will uniquely benefit from the application of computational approaches because of the combinatorial nature of target binder, linker, and E3 ligase, as well as the ability to bind to the protein of interest outside the active site. Computational techniques can also help predict protein surface conformation changes in the identification of novel molecular glues. Our first VantAI-designed degraders have generated early-stage preclinical data that suggests our computational approach can generate candidates that achieve real-world degradation against multiple relevant targets.

We expect to face competition within a growing class of degrader-focused companies. We believe that our computational capabilities provide critical differentiation in an area that is uniquely suited to the application of computational techniques. The combinatorial nature and modularity of degrader structures allows for computational techniques to provide meaningful acceleration in the identification, design and optimization of protein degraders. To our knowledge, no competitor has a computational platform as advanced or robust as the capabilities we have built through our small molecule discovery engine. Today, our preclinical and clinical development organizations, initial pipeline, and long-term access to a leading academic lab are integrated with our computational capabilities. Further, VantAI algorithms have incorporated over five years of real-world laboratory data generated by Dr. Wang's lab, in turn informing the identification of targets and discovery of novel degraders to further evaluate in the lab and ultimately advance into the clinic.

AR Degrader for the Treatment of Prostate Cancer

Our lead degrader candidate, ARD-1671, is an orally-administered androgen receptor ("AR") protein degrader currently undergoing IND-enabling studies. ARD-1671 is designed to shut down the AR pathway by targeting and degrading the AR protein, the primary driver of prostate cancer. Based on its *in vitro* potency and selectivity, as well as its encouraging safety and tolerability demonstrated to date in canine and rat non-GLP dose range finding studies described below, we believe ARD-1671 has the potential to provide meaningful clinical benefit to prostate cancer patients.

Prostate cancer overview

Prostate cancer is the second most common form of cancer in men, with nearly 200,000 annual new cases in the US alone. Additionally, with over 30,000 annual U.S. deaths, prostate cancer is the second most common cause of cancer death in the US. Prostate cancer occurs more frequently in older men and is associated with
various other risk factors, including a family history of prostate, breast, or ovarian cancer, high-fat diets or obesity, smoking and maintenance of a sedentary lifestyle. While prostate cancer can be slow-growing, such that some men die of other causes before their cancer, many patients experience metastases to other parts of the body. Prostate cancer that continues to progress following androgen deprivation therapy ("ADT") is considered to be castration-resistant. It is estimated that over 40,000 cases of metastatic castration-resistant prostate cancer ("mCRPC") occur annually in the US, with over 20% of all prostate cancer deaths occurring in men with mCRPC.

The AR signaling axis is critical to the development, function and homeostasis of the normal prostate. After binding androgen, cytoplasmic AR translocates to the nucleus, where it activates transcription of target genes. The AR also plays a role in prostate carcinogenesis and progression to androgen-resistant disease and is expressed in nearly all primary prostate cancers.

Limitations of current treatments

The current prostate cancer treatment paradigm involves the use of AR-targeted therapies throughout the progression of the disease. For more advanced forms of prostate cancer, ADT is one of the primary treatment options. Among the most common ADTs are AR antagonists such as Xtandi (enzalutamide), which functions by blocking AR, and androgen synthesis inhibitors, including Zytiga (abiraterone acetate). While these treatments have been successful in improving patient outcomes, resistance remains a major concern. At least 10% of patients whose disease has spread beyond the prostate on first-line ADT do not experience suppression of prostate-specific antigen ("PSA"), an AR-regulated gene. Additionally, while dramatic initial responses to ADT are often observed, these responses are often not sustained, with median duration of response of up to 18 months, and virtually all patients treated with ADTs ultimately progressing to castration resistance. For patients who do not respond, chemotherapy is often chosen as the next line of treatment, although its use is often postponed due to its severe side effects.

Of patients with mCRPC, including those whose cancer progresses following treatment with androgen receptor signaling inhibitors, between 40% and 50% have alterations involving the AR, suggesting that their tumors may still be driven by AR signaling. Furthermore, progressive disease experienced by patients while undergoing treatment with Xtandi or Zytiga is often accompanied by increase in serum PSA, further suggesting continued AR-driven cellular proliferation. We believe that AR degraders have the potential to improve the response rates and durability achieved with existing AR antagonists and inhibitors by degrading the AR, thereby fully shutting down the AR pathway, both in refractory and earlier-line prostate cancer patients.

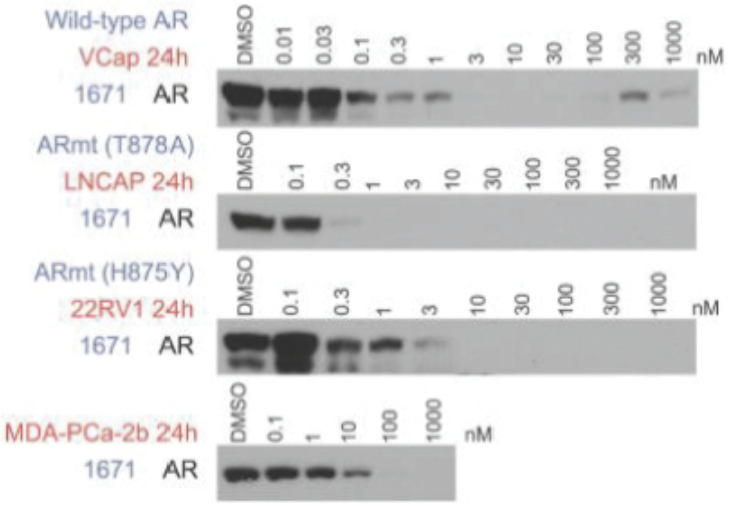
Preclinical data

In preclinical testing, ARD-1671 has demonstrated high potency and selectivity and has produced encouraging tolerability data in toxicology studies completed to date.

ARD-1671 has shown *in vitro* activity in wild type AR as well as multiple clinically relevant AR cell lines with known mutations. The table below shows the DC_{50}, or the concentration at which half-maximal degradation is achieved at 24 hours, of ARD-1671 in four different cell lines: vertebral cancer of the prostate ("VCaP"), which exhibits wild-type AR; and three cell lines exhibiting mutant AR: lymph node cancer of the prostate ("LNCaP"), 22RV1 and MDA-PCa-2b. Each of these cell lines are well defined populations of cells that have been immortalized from human prostate cancer patients.

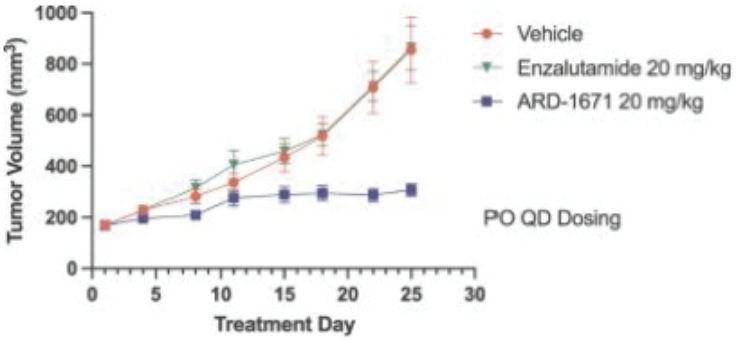
Cell Line	AR Variant	DC50 (nM)
VCaP	Wild type	0.05
LNCaP	T878A	0.082
22RV1	H875Y	0.9
MDA-PCa-2b	L702H/T878A	6

The western blots below demonstrate ARD-1671's degradation ability in each of these cell lines. As the concentration of ARD-1671 increases to the right across each blot, the presence of AR, as indicated by the size and opacity of each band, decreases.



In a head-to-head study with an intact VCaP xenograft model in severe combined immunodeficient ("SCID") mice, which has high AR expression and in which enzalutamide is inactive, ARD-1671 demonstrated tumor growth inhibition (64%) compared to enzlutamide (-1%) on treatment day 25.

Antitumor Activity in VCaP Xenograft Tumor Model



In a 21-day non-GLP dose range finding canine study, maximal prostate weight reduction was achieved at the lowest dose of 1 mg/kg, consistent with the expected pharmacodynamic effect. No significant adverse events were observed at dose levels up to 10 mg/kg. In a 21-day non-GLP dose range finding rat study, no significant adverse events were observed at dose levels up to 300 mg/kg and prostate weight reduction was also attained.

These results indicate that ARD-1671 may have a wide therapeutic window, which is currently being assessed in GLP toxicology studies.

Development plan

Our lead AR candidate ARD-1671 is in IND enabling development. We intend to pursue the development of our AR program in refractory prostate cancer and to explore its potential in early-line settings, such as mCRPC or non-metastatic castration-resistant prostate cancer, as well as in a combination therapy. We expect to initiate a Phase 1 study for our AR program in 2022.

STAT3 Degrader

We are developing signal transducer and activator of transcription 3 ("STAT3") degraders for the treatment of STAT3-driven hematologic malignancies and immuno-oncology indications. Due to potency and selectivity challenges, STAT3 has traditionally been considered to lack an easily druggable pocket. We believe that preclinical data we have generated to date suggest the potential of STAT3 degraders to overcome these challenges.

STAT3-Implicated diseases

STAT3 is a transcription factor that regulates many biological processes and has been implicated as a direct driver of multiple tumor types. STAT3 controls, among other processes, differentiation, survival, proliferation and angiogenesis, typically in response to growth factors and cytokines. Activation of STAT3 normally involves Janus kinase (JAK)-mediated phosphorylation and dimerization of STAT3 following binding of IL-6 to its receptor. Aberrant constitutive activation of STAT3 has been observed in many different cancers and has been associated with poor prognosis and tumor progression. STAT3 activation is also reported as a mechanism of resistance to inhibitors of the receptor tyrosine kinases EGFR and ALK.

STAT3 contributes to an immunosuppressive microenvironment ("TME"), suggesting STAT3 degraders have significant potential as immune-oncology agents. Phosphorylated STAT3 ("pSTAT3") acts to negatively regulate neutrophils, natural killer, effector T and dendritic cells. STAT3 also promotes myeloid-derived suppressor cells ("MDSCs") and regulatory T cells and has been shown to mediate the up-regulation of immunosuppressive factors such as IL-10 and TGF-ß. Additionally, a STAT3 antisense oligonucleotide inhibitor demonstrated early evidence of clinical activity in lymphoma and lung cancer.

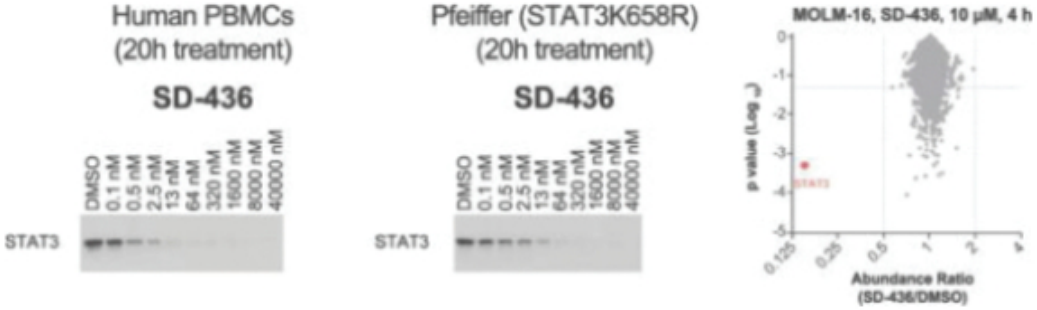
Given the broad activity of STAT3, we believe a STAT3 degrader has significant potential in numerous solid tumors and hematologic malignancies, including non-Hodgkin lymphoma, multiple myeloma, and breast, lung, hepatocellular and head and neck cancer.

Limitations of current STAT3 approaches

Due to STAT3's lack of an easily druggable pocket, previous attempts to target STAT3 have been largely unsuccessful. One common approach, inhibition of dimerization with small molecules targeting the SH2 domain of STAT3, has been limited by the transcriptional activity of monomeric STAT3 and by specificity challenges due to the high homology of SH2 domains across STAT proteins. Another common approach, attempting to regulate STAT3 via inhibition of JAK, which is upstream of STAT3, has demonstrated significant off-target effects and STAT3 activation and homodimerization can occur independently of JAK. A third common approach, the use of STAT3 antisense oligonucleotides, has been limited by low cell penetration due to large size, low bioavailability and poor pharmacokinetics, and short half-life *in vivo*. We believe that the degrader modality has the potential to address many of the historical challenges associated with STAT3 targeting.

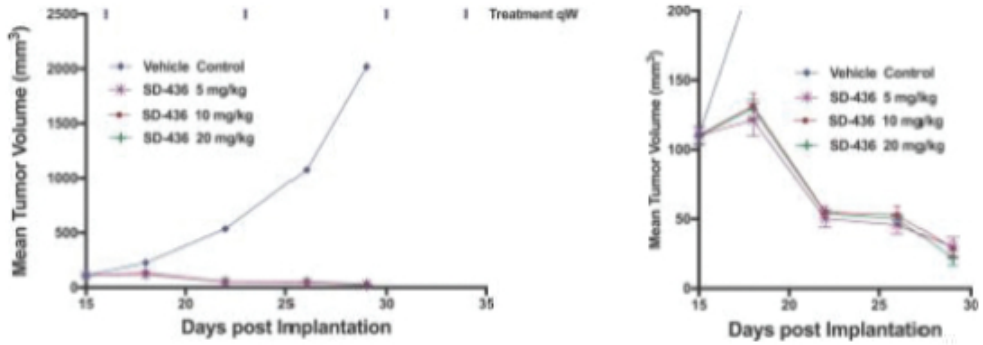
Preclinical data

Our STAT3 degrader discovery program has identified a lead compound, SD-436, that potently and rapidly degrades the target with high specificity with respect to degradation of other STAT proteins. SD-436 exhibits promising potency against wild type STAT3 in human peripheral blood mononuclear cells ("PBMCs") as well as a mutated STAT3 protein (K658R) in the Pfeiffer cell line, with degradation achieved at low nM concentrations. Furthermore, in an unbiased proteomics analysis in which megakaryoblastic leukemia cell line MOLM-16 cells were treated with SD-436, STAT3 was the only protein observed to be degraded with statistical significance among the approximately 5,000 proteins analyzed, indicating SD-436's high specificity.



In a leukemia xenograft tumor model with an activated STAT3 pathway, IV administration of SD-436 resulted in deep reductions in tumor volume. The lowest dose tested, 5 mg/kg weekly, achieved rapid and complete tumor regression.

Effect of IV SD-436 on Tumor Volume in MOLM16 Xenograft Model



Development plan

We plan to explore the potential use of a STAT3 degrader as monotherapy, combination therapy, or, in sequence with chemotherapy or radiation, in tumors that are driven by the STAT3 pathway. In addition, we are exploring the potential for the STAT3 degrader as a potentially important immuno-oncology program both alone and in combination studies.

Additional Discovery Programs

In addition to AR and STAT3, we are pursuing numerous additional targets with strong scientific rationale and potentially attractive market opportunities. We do not expect to ultimately advance programs for all of these targets into clinical development. We are also discovering drug candidates for additional undisclosed targets and plan to continue to add new discovery programs over time.

Target & MoA	Opportunity Profile	Potential Indications/Patient Populations
CBP/P300 Degrader	• CBP/P300 control expression of oncogenic factors (e.g., AR, c-Myc) in prostate cancer • Synthetic lethality target (LOF mutations) with precision medicine approach	• AR+ prostate cancer (including AR mutants and splice variant subsets), tumors with CBP or P300 LOF (e.g., DLBCL, FL, NSCLC, bladder cancer)
SMARCA2/4 Degrader	• Synthetic lethality target in multiple tumor types (e.g., SMARCA4 LOF)	• SMARCA4-mutated NSCLC (~10% of NSCLC overall) • Tumor agonistic indication: SMARCA4- mutated solid tumors
KRAS G12D Degrader	• Historically undruggable oncogene variant G12D • Most frequently mutated oncogene in human cancers	• KRAS G12D mutant tumors • Highest rates in PDAC, CRC, endometrial and lung cancer

Genevant Overview

- **Overview:**
  - Genevant is a technology-focused nucleic acid delivery and development company with a lipid nanoparticle ("LNP") platform, an expansive intellectual property portfolio and deep scientific expertise, currently focused on partnering with other pharmaceutical or biotechnology companies to enable the development of nucleic acid therapeutics for unmet medical needs.
- **Delivery platforms:**
  - Genevant has two delivery platforms: LNP and ligand conjugate.
    - LNP platform:
      - Proven technology as demonstrated by head-to-head *in vivo* ionizable lipid study assessing LNP potency and immune stimulation
      - Clinically validated for hepatocyte and vaccine applications and under development for other traditionally hard-to-reach tissues and cell types, including lung, eye, central nervous system, and hepatic stellate and immune cells
      - Over 700 issued patents and pending patent applications as of October 15, 2021
    - Ligand conjugate platform:
      - Novel GalNAc ligands with demonstrated ability to deliver to the liver in preclinical studies
      - In preclinical head-to-head testing, demonstrated equal or better preclinical potency, assessed by duration and magnitude of knockdown, compared to a current industry benchmark
      - Applying delivery expertise to design of novel extrahepatic ligands to expand therapeutic reach
- **Collaboration-based business model:**
  - Genevant uses its expertise in the delivery of nucleic acid therapeutics to develop optimal delivery systems for its collaborators' identified payloads or target tissues.
  - Genevant collaboration-based business model is to seek some or all of upfront payments, R&D reimbursements, and milestones and royalties (or profit share) upon success, while also retaining certain rights in the delivery-related intellectual property developed in the context of the collaboration for potential out-license.
  - Some current collaboration partners include BioNTech, Takeda, Sarepta, Gritstone, ST Pharm, and Providence Therapeutics.
- **Clinical data:**
  - Genevant LNP technology has been in clinical testing in over a dozen distinct product candidates, representing hundreds of subjects of clinical experience.
  - Genevant LNP technology is included in the first siRNA-LNP product to receive FDA-approval, Alnylam's Onpattro (patisiran).
- **Roivant ownership:**
  - As of September 30, 2021, we own 83% of the issued and outstanding Common Shares of Genevant and 67% on a fully diluted basis.

Nucleic Acid Therapeutics

Nucleic acid therapeutics represent an attractive, novel modality that we believe may overcome challenges associated with traditional small molecule drug development in the treatment of genetically defined disease. The vast majority of human proteins are considered “undruggable” by small molecules based on their protein structure. Nucleic acid therapeutics circumvent the question of whether or not a target is undruggable by impacting protein expression itself.

The field of nucleic acid therapeutics has gained significant momentum in recent years, with FDA approval of Alnylam’s Onpattro and Givlaari (givosiran), and approval or emergency use authorization of multiple mRNA COVID-19 vaccines. There is a substantial pipeline of nucleic acid therapeutics in clinical development that further underscores the transformative potential of nucleic acid therapeutics in the near term. However, nucleic acid therapeutics remain challenged by obstacles in the delivery of nucleic acids to specific cell types. RNA molecules cannot passively cross most cell membranes given their large size and negative charge, and therefore must be administered in conjunction with a delivery technology to ensure transport to target cell types.

We work with two proprietary technologies, LNP delivery and ligand conjugate delivery, to improve the likelihood of clinical success of nucleic acid therapeutics. Some of the intellectual property with respect to each of these technologies was licensed from Arbutus Biopharma in 2018.

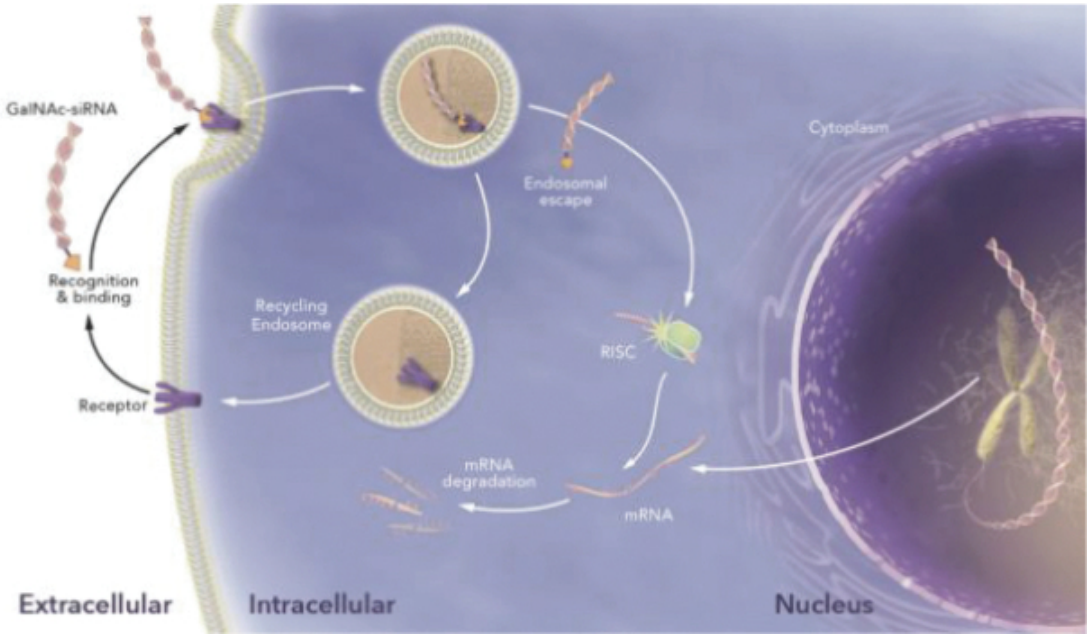
We have continued to advance our platforms, expanding into novel tissue types by leveraging the scientific expertise of several members of the technical team that originally developed or advanced the technologies at Arbutus and its predecessors.

Lipid Nanoparticle Platform

Our LNP technology platform is designed to deliver nucleic acids, including mRNA, siRNA, antisense and gene editing constructs.

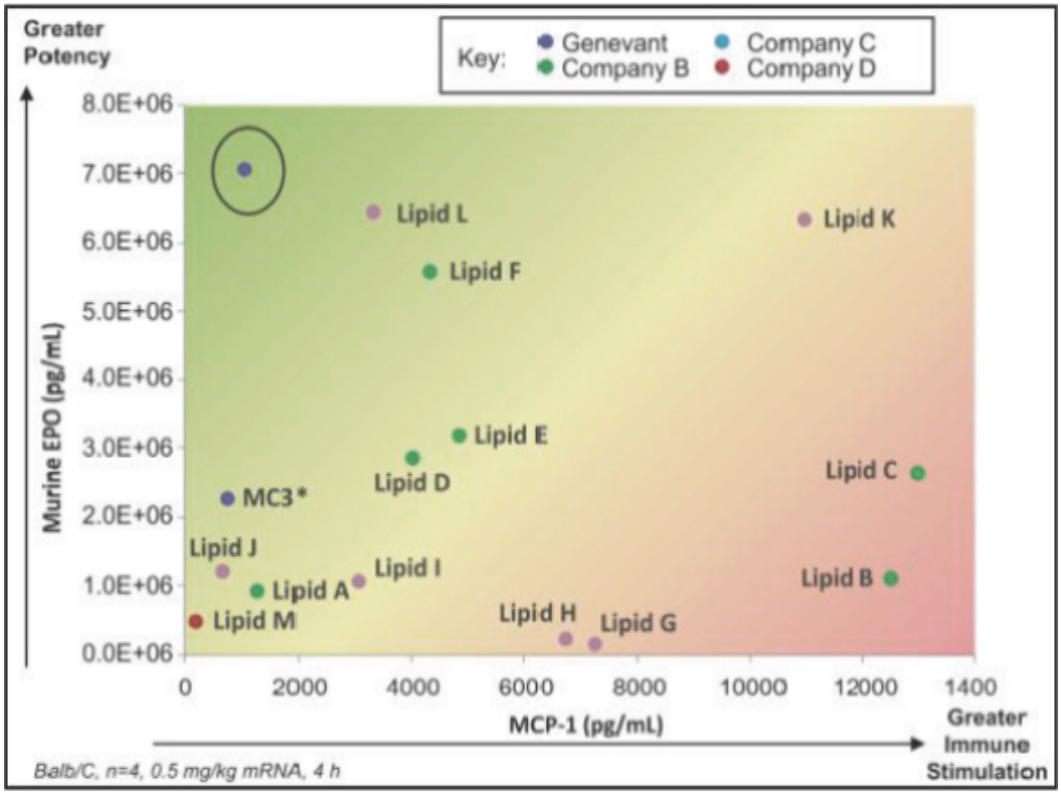
Some key features of our LNP technology are:

1. Multi-component formulations that contain specialized lipids optimized for potency and tolerability, are capable of encapsulating a broad range of nucleic acid payloads, and have limited constraints on nucleic acid composition, structure or size
2. A manufacturing process developed and scaled to produce stable uniform dispersion of colloidal nanoparticles with particle size appropriate for parenteral or intramuscular administration
3. Efficient intracellular delivery of nucleic acids to cell cytoplasm via engineered active endosomal escape mechanism



In a head-to-head study comparing multiple LNP formulations varying only the key ionizable lipid, a newer Genevant formulation outperformed third party formulations. In particular, our formulation showed superior potency and avoidance of immune stimulation relative to others, including when compared with the LNP utilized in the first FDA-approved siRNA-LNP therapeutic, Alnylam's Onpattro ("MC3" in figure below).

Genevant LNP Outperformed Third Party LNPs in Head-to-Head Study



* Key lipid of first FDA-approved siRNA-LNP (Alnylam's Onpattro)

In addition, Genevant LNP technology has entered the clinic in more than a dozen distinct product candidates, representing hundreds of subjects of clinical experience.

Substantial clinical experience with Genevant LNP technology

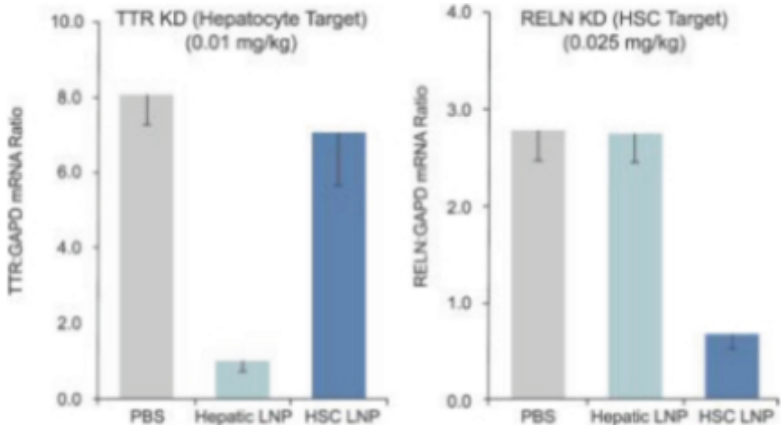
Company	Product	Indication	Activity	Latest Phase
Alnylam	ONPATTRO (patisiran)	ATTR Amyloidosis	• Safely dosed for up to 25 months in some patients • Efficacy of up to 94% TTR knockdown with physiological effect • Approved by the FDA August 2018	Approved
Arbutus	ARB-1467 (TKM-HBV)	Hepatitis B	• Completed Phase 2b trial in HBV patients • Clear PD effect (knock down of surface antigen)	Phase 2
	TKM-PLK1	Oncology	• Safely dosed for up to 18 months • Evidence of anti-tumor activity based on a decrease in tumor size and a decrease in tumor density consistent with necrosis	Phase 2
	TKM-Ebola (three LNP products)	Ebola Infection	• 100% protection in lethal primate model of EVD • Compassionate use in 2014 Ebola outbreak	Phase 2
moderna	Four Prophylactic mRNA Vaccines	Various infectious diseases	• Successful completion of first in human mRNA vaccine trial • Met primary endpoint of neutralizing Ab titers in healthy subjects	Phase 1
gritstone	GRANITE-001	Oncology	• Personalized oncology vaccine; self replicating RNA payload encoding tumor neoantigens • Promising immunogenicity activity and safety data released	Phase 2
	PTX-COVID19-B	SARS-CoV-2	• Promising immunogenicity activity and safety data released	Phase 1

With this track record of success, we are now also focusing our LNP capabilities on historically challenging cell and tissue types, including hepatic stellate cells and the lung.

Historically, attempts to address certain diseases have been limited by the inability to access specific cell types outside of the hepatocyte. We have demonstrated our ability to deliver nucleic acid therapeutics to challenging targets by accessing hepatic stellate cells (“HSCs”) in preclinical studies. The activation of HSCs is well established as a central driver of fibrosis, and thus technologies that target activated HSCs may be key to address certain liver diseases.

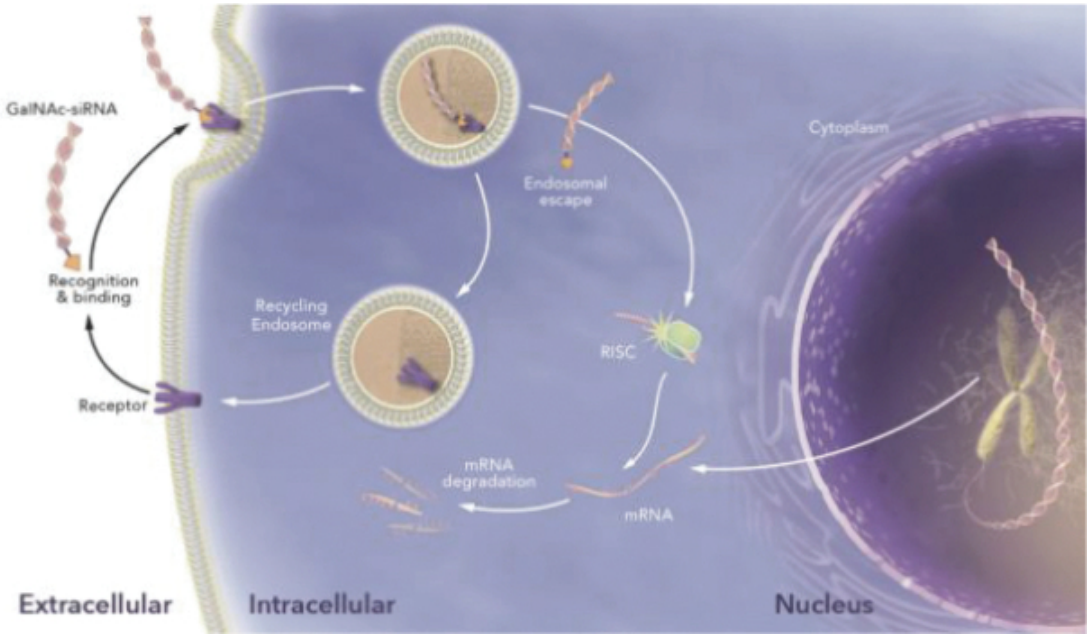
In preclinical studies, delivery of RNAis to HSCs via Genevant’s LNP technology demonstrated selective knockdown of an HSC target with minimal activity in hepatocytes, as shown below. Additional preclinical studies support our ability to design LNPs to deliver nucleic acids to the lung, and we believe that our scientific expertise will over time lead to the ability to direct LNPs toward additional cell and tissue types, such as the central nervous system and eye.

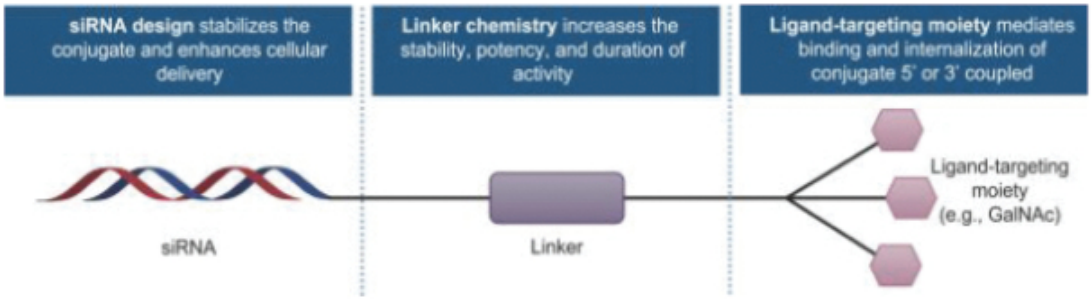
LNP delivery of siRNA to HSCs demonstrated selective knockdown of target mRNA in mice with minimal activity in hepatocytes



Ligand Conjugate Platform

In addition to our LNP platform, we also have a proprietary RNAi ligand conjugate platform. Novel ligands can successfully deliver siRNA and certain other oligonucleotides to the liver, and our delivery expertise enables the design of novel ligands potentially to expand therapeutic reach to hepatic stellate cells. Our ligand conjugate technology has demonstrated equal or better preclinical potency, assessed by duration and magnitude of knockdown compared to current industry benchmark. We currently have multiple patent applications pending with respect to our ligand conjugate platform.

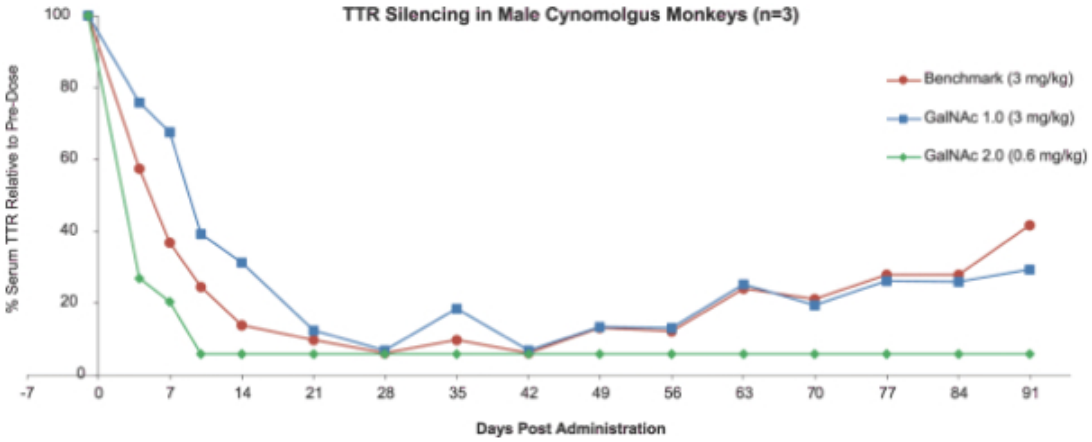




We are developing a next-generation ligand conjugate ("RNAi 2.0") platform. Our RNAi 2.0 platform has demonstrated superior strength and duration of knockdown compared to legacy ligand conjugates ("RNAi 1.0") in a head-to-head nonclinical study in nonhuman primates. In addition, our RNAi 2.0 platform:

- Contains intrinsic endosomolytic properties
- Has demonstrated marked *in vivo* enhancement in potency
- Has maintained a subcutaneous dosing regimen and is expected to be dosed subcutaneously in clinical trials
- Remains compatible with other ligand types

Next Generation RNAi 2.0 Conjugate Platform Shows Improved Potency, Magnitude and Duration of Knockdown



Strategy

Genevant seeks to partner with other pharmaceutical or biotechnology companies in the development of RNA therapeutics, crafting mutually beneficial collaborations that allow collaboration partners to access innovative technologies while providing Genevant the opportunity to leverage our expertise to expand the technology and corresponding therapeutic reach.

This provides the following benefits to collaborators:

- Access to validated technology to deliver nucleic acid therapeutics for hepatocyte or vaccine applications

- Potential to deliver RNA payloads to historically challenging-to-reach tissue or cell types, as well as nucleic acid design capabilities
- No need to build internal delivery expertise or build intellectual property estate from scratch in an increasingly complex field

This provides the following benefits to Genevant:

- Opportunity to expand core delivery technology and capabilities, maintaining leadership position in nucleic acid delivery
- Typically, certain rights to delivery-related intellectual property developed in the context of collaboration and the ability to exploit these rights through other out-license
- Opportunity to generate revenue through deal structures including some combination of upfront payments, R&D reimbursements and additional milestones and royalties upon successful outcomes

To date, Genevant has partnered with leading companies with a shared vision of advancing innovative nucleic acid medicines to transform the lives of patients. Our collaborations currently include:

- **Gritstone**—Access to Genevant's LNP technology for use in Gritstone's self-amplifying RNA COVID-19 vaccine program
- **Gritstone**—Access to LNP technology for use with self-amplifying RNA for an unspecified indication
- **Sarepta**—Research collaboration and option agreement for the delivery of LNP-gene editing therapeutics for specified neuromuscular diseases; Genevant will design and collaborate with Sarepta in the development of muscle targeted LNPs to be applied to gene editing targets in multiple indications, including Duchenne muscular dystrophy
- **BioNTech**—Co-development in up to five rare diseases with high unmet medical need, and access to LNP technology for use with BioNTech's mRNA for a specified number of oncology targets
- **Takeda**—Access to LNP technology to develop nucleic acid therapeutics directed to specified targets in hepatic stellate cells to treat liver fibrosis
- **Takeda**—Access to LNP technology to develop nonviral gene therapies for up to two rare liver diseases
- **ST Pharm**—Access to Genevant's LNP technology for use in specified territories in an mRNA COVID-19 vaccine
- **Providence**—Access to Genevant's LNP technology for use in Providence's mRNA COVID-19 vaccine program

Potential Benefits of Genevant's Delivery Platforms

- *Robust and expansive patent estate.* As of October 15, 2021, over 700 issued patents and pending patent applications for our LNP platform, including coverage of individual lipid structure, particle composition, particle morphology, manufacturing and mRNA-LNP formulations. As we continue to develop these technologies, we expect to have the opportunity to expand intellectual property protection further, to enhance protection and support additional licensing opportunities.
- *Experienced leadership team.* Our leadership team has deep technical expertise in nucleic acid drug development and a track record of executing successfully in innovative areas. We believe this positions Genevant to expand delivery to historically challenging tissues and cell types, thereby creating potential opportunities for creative collaboration.

- *Manufacturing know-how.* Since inception, we have made strategic investments in expanding our manufacturing know-how. Our manufacturing process is rapid and reproducible, has intellectual property protection and is capable of commercial scale.

Expansive Patent Portfolio

Our LNP platform is protected with a robust patent portfolio, covering a wide range of aspects required for successful nucleic acid delivery.

Our patents are directed to:

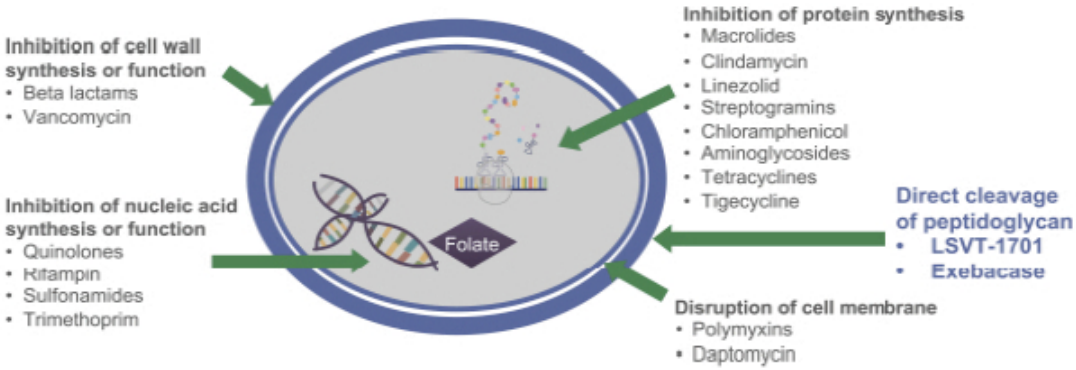
- Structures and individual lipid compositions, including cationic and PEG-lipids
- Particle compositions, including commonly used, most active ranges of lipid ratios for nucleic acid-containing particles
- Nucleic acid-containing particles with certain structural characteristics
- mRNA-containing LNP formulations
- Various aspects of our manufacturing process

Lysovant Overview

- **Overview:**
  - Lysovant is developing LSVT-1701, a novel endolysin, for the treatment of *Staph aureus* bacteremia ("SAB") to potentially address significant unmet medical need in the treatment of serious bacterial infections.
- **Lead program:**
  - *LSVT-1701:* Novel bacteriophage-derived biologic candidate with potent, selective and rapid bactericidal anti-staphylococcal activity including multi-resistant strains via cell wall hydrolysis.
- **Disease overview:**
  - *Staph aureus* is a major cause of infections in the United States and can be serious or fatal by causing bacteremia or sepsis when the bacteria enter the bloodstream. Unless promptly treated, SAB can metastasize to deep tissues and significantly increase the risk of mortality. The most common complications include infective endocarditis ("IE"), vertebral osteomyelitis and pulmonary infections.
  - In the United States, there are an estimated 226,000 patients with SAB and 50,000 with IE per year. The incidence of SAB is increasing due to the growth of invasive procedures, expansion of implanted medical devices and rise in number of immunocompromised patients.
- **Limitations of current treatments:**
  - Current standard of care antibiotics for SAB are vancomycin and daptomycin for MRSA, and beta-lactam antibiotics for MSSA, and there has been no innovation for decades. Current antibiotic treatments take days to suppress the bacteria in hospitalized SAB patients. There exists significant unmet need for rapid bactericidal antibiotics for complicated SAB and IE, as patients require more effective treatments to reduce the high mortality of these diseases.
- **Clinical data:**
  - Results from Phase 1/2a clinical trials suggest that LSVT-1701 is generally well-tolerated with an adequate safety profile on top of standard of care antibiotics.
- **Development plan and upcoming milestones:**
  - We anticipate initiating a Multiple Ascending Dose (MAD) study of LSVT-1701 in patients with complicated SAB including IE in the first half of calendar year 2022.
- **Roivant ownership:**
  - As of September 30, 2021, we own 100% of the issued and outstanding common shares of Lysovant and 99% on a fully diluted basis.
- **Pipeline:**

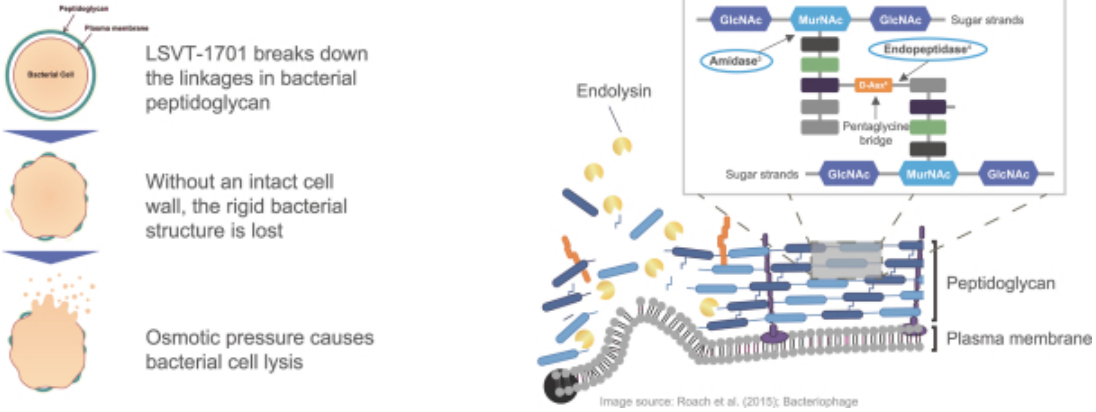
LSVT-1701

LSVT-1701 is a selective and efficient bactericide due to its unique endolysin mechanism. Where other antibiotics and treatments inhibit the synthesis or function of the bacteria's cell wall, nucleic acid, membrane, and protein, LSVT-1701 directly cleaves the bacteria's cell wall leading to rapid bacterial lysis.



We believe LSVT-1701 may be the most effective lysin due to its use of two catalytic domains, called amidase and endopeptidase. These domains provide peptidoglycan (cell wall) hydrolysis. While the amidase cuts between the sugar stands and stem peptides, the endopeptidase cleaves the bonds between the stem peptide and the pentaglycine bridge. As shown below, this novel endolysin mechanism potentially allows for more rapid bactericidal effect. Additionally, endolysin target binding sites are highly conserved and essential to *S. aureus* bacteria viability. We believe this may contribute to lower propensity for resistance.

LSVT-1701 Mechanism of Action



LSVT-1701 for the Treatment of *Staph aureus* Bacteremia

Staph aureus bacteremia and limitations of current treatments

Staph aureus is a major cause of infections in the United States and can be serious or fatal by causing bacteremia or sepsis when the bacteria enter the bloodstream. Other complications from infection include

infective endocarditis, where the infection reaches heart valves and may cause heart failure or stroke, and osteomyelitis, where the bone becomes infected. Common strains of *Staph aureus* are either methicillin-resistant ("MRSA") or methicillin-susceptible ("MSSA").

In the United States, there are an estimated 226,000 patients with *S. aureus* bacteremia and 50,000 with infective endocarditis per year. Of all SAB cases, around 45% are caused by MRSA and 55% by MSSA. Complicated bacteremia due to sepsis, comorbidities or dialysis accounts for approximately 32% of SAB cases per year and refractory bacteremia accounts for approximately 28% of SAB cases per year. In addition to being a leading cause of infections, SAB is also a major cost driver to U.S. hospitals and results in high mortality rates. Average 30-day mortality of *S. aureus* infections is around 20% with current antibiotic treatment. Complicated bacteremia is associated with higher mortality rates of up to 30%. MRSA and MSSA bacteremia is associated with long hospital stays and high ICU utilization, particularly for complicated bacteremia and IE. Cost of care for SAB across MRSA and MSSA is around $7.4 billion annually, with sepsis due to the bacteria accounting for 79% of this annual cost. These burdens are in part due to rising resistance of infections to current standard of care antibiotics. Consequently, there is a great need for new therapies efficacious for both hard-to-treat MRSA and MSSA.

We believe that if approved for commercial sale, LSVT-1701 would be differentiated from both current standard of care and emerging endolysin treatments for SAB and IE. Endolysins have been clinically validated as a novel class of bacterial treatment by results from ContraFect's Phase 2 trial of exebacase, which showed efficacy in MRSA but not MSSA and in right-sided infective endocarditis compared to standard of care antibiotics alone. While exebacase's endolysin mechanism only cleaves at one site in the cell wall, LSVT-1701 cleaves at two, potentially increasing its bactericidal capability. Based on preclinical and clinical trials, we believe that if approved, LSVT-1701 can also be given in multiple doses and at higher dosing levels compared to exebacase, which cannot be dosed twice and has a compound-specific dose-limiting toxicology signal (vasculitis). If approved, we believe that LSVT-1701 could be an attractive treatment on top of standard of care for populations with high medical needs, such as those with complicated MRSA and MSSA bacteremia, and left-sided infective endocarditis.

As a result of the novel endolysin mechanism of LSVT-1701, we believe that LSVT-1701, if approved for use, could provide the following potential benefits:

- *Rapid antibacterial activity.* Where current antibiotic treatments take a long time to suppress the bacteria, LSVT-1701 has the potential to provide rapid and highly effective lytic action.
- *Species specificity.* Anti-staphylococcal endolysins provide pathogen-targeted bacteriolysis and preserve normal flora
- *Low propensity for resistance.* Target binding sites are highly conserved and essential to bacteria viability.
- *Synergy with standard of care.* LSVT-1701 has the potential to be used to treat antibiotic-resistant bacteria and administered concurrently with antibiotics.
- *Effective against biofilms.* In animal models, LSVT-1701 eradicated and cleared biofilm where standard of care is ineffective.
- *Effective against all strains. In vitro* susceptibility data demonstrate an activity profile for both MRSA and MSSA, and multi-resistant clinical isolates.

Clinical data

Phase 1

In February 2019, iNtRON Biotechnology completed Phase 1 studies evaluating the safety, pharmocokinetics and pharmacodynamics of LSVT-1701. In these double-blind, placebo-controlled studies, 51 healthy subjects were given single or multiple ascending doses. All adverse events reported were mild or

moderate and included chills or rigors, infusion site reaction, pyrexia, headache, myalgia and fatigue. These adverse events appeared dose-dependently but were not frequency-dependent. There were no reported severe adverse events reported.

Phase 2a

In November 2019, Lysovant completed a randomized, placebo-controlled Phase 2a clinical trial evaluating the safety of LSVT-1701 in *S. aureus* bacteremia. In this trial, 12 subjects with persistent MRSA or MSSA bacteremia received a single IV dose of LSVT-1701 3 mg/kg in addition to standard of care antibiotics. 13 subjects received placebo, alongside standard of care antibiotics. LSVT-1701 was generally well-tolerated, with similar proportion of subjects reporting adverse events in both placebo and LSVT-1701 arms. Additionally, there was also no evidence of cytokine storm or anaphylaxis. The safety profile observed potentially allows for higher dosing in future trials.

Preclinical data

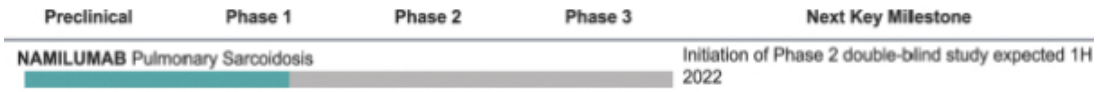
In a non-neutropenic murine bacteremia (i.e., MSSA sepsis) model, postantibiotic effect ("PAE") occurred after 48 hours. PAE occurs when bacterial growth is successfully suppressed after drug administration. There were no dose-limiting toxicities like vascular lesions or immunogenicity following administration of multiple doses, which suggests safety and tolerability within the model. In a rabbit infectious endocarditis model, a multi-dose regimen of LSVT-1701 demonstrated complete sterilization of tissues. The data also suggest the ability to dissolve bacterial vegetations, as LSVT-1701 achieved complete experimental sterilization on top of daptomycin, whereas the daptomycin antibiotic regimen alone and exebacase on top of daptomycin did not (not a head-to-head study). *In vitro*, LSVT-1701 has demonstrated a narrow and well-defined minimum inhibitory concentration (MIC) range (MIC_{90} 2 ug/ml) across a diverse collection of current clinical *S. aureus* isolates including MRSA, MSSA, vancomycin-intermediate *S. aureus* (VISA), and glycopeptide-intermediate *S. aureus* (GISA). LSVT-1701 also exhibited a comparable MIC range in 82 coagulase negative staphylococci (CoNS) isolates. MIC measures the lowest concentration of drug necessary to prevent visible bacterial growth, and a narrower MIC range suggests that LSVT-1701 is an efficient bactericide against multi-resistant clinical isolates. LSVT-1701 was also not adversely affected by decreased susceptibility or resistance to various antibiotics, further confirming its bactericidal activity.

Development plan

LSVT-1701 is being developed for the treatment of SAB and IE, and we plan to initiate a Multiple Ascending Dose (MAD) study in the first half of calendar year 2022.

Kinevant Overview

- **Overview:**
  - Kinevant is focused on developing namilumab for pulmonary sarcoidosis and other autoimmune diseases.
- **Lead program:**
  - *Namilumab:* Fully human anti-GM-CSF monoclonal antibody with broad potential in autoimmune diseases.
- **Disease overview:**
  - Sarcoidosis is a multisystem autoimmune disease that affects approximately 200,000 people in the United States, with 95% of cases presenting with pulmonary involvement.
- **Limitations of current treatments:**
  - Corticosteroids are the most widely used treatment for sarcoidosis, but they carry significant side effects when used longer-term. Second- and third-line treatment options, including immunosuppressive therapies and biologics, are limited by slow onset, safety risk, inconsistent effectiveness, and reimbursement challenges, leaving significant unmet medical need that could be met by a novel biologic.
- **Clinical data:**
  - Early clinical data in pharmacokinetic/pharmacodynamic (PK/PD) and subsequent Phase 2 studies showed namilumab to be well tolerated with a single subcutaneous injection given up to every four weeks.
- **Development plan and upcoming milestones:**
  - We plan to initiate a Phase 2 trial to test for the safety and efficacy of namilumab in pulmonary sarcoidosis in the first half of calendar year 2022.
- **Roivant ownership:**
  - As of September 30, 2021, we own 88% of the issued and outstanding common shares of Pharmavant 3 (renamed Kinevant in October 2021), and 88% on a fully diluted basis.
- **Pipeline:**

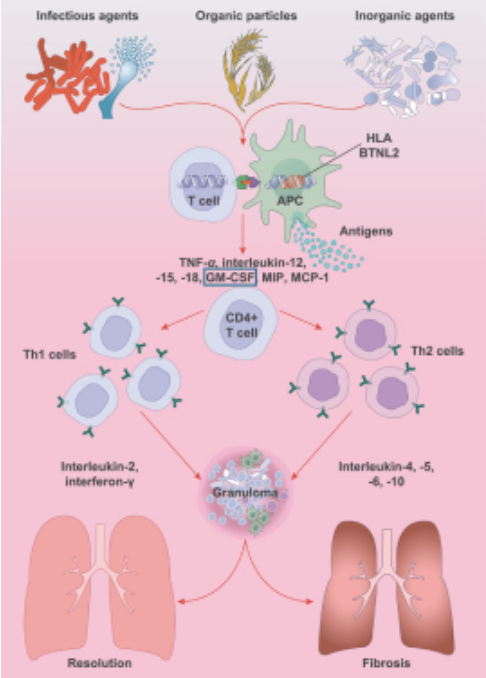


Namilumab

Namilumab is a fully human monoclonal antibody that neutralizes granulocyte-macrophage colony-stimulating factor (“GM-CSF”) activity by preventing it from binding to high-affinity cell surface receptors, neutralizing the otherwise pathogenic cytokine in conditions such as pulmonary sarcoidosis.

GM-CSF provides key functions as a pro-inflammatory cytokine and growth factor. Following antigen stimulation or activation by cytokines, GM-CSF can be secreted by a variety of cell types, including activated B and T cells. GM-CSF is pro-inflammatory as it activates macrophages and other cells to drive inflammation and tissue damage. GM-CSF also acts as a growth factor; for example, recombinant GM-CSF is used for the treatment of low white blood cell counts in cancer patients undergoing chemotherapy to increase white blood cells and mobilize them into peripheral blood.

GM-CSF's Role in Sarcoid Pathogenesis



Due to its targeting of a common pro-inflammatory cytokine, we intend to evaluate the development of namilumab for the treatment of a number of potential autoimmune indications. GM-CSF administration has been found to drive disease progression in a variety of preclinical models, including inflammatory arthritis, multiple sclerosis, interstitial lung disease, nephritis, myocarditis, and giant cell arteritis, among others, suggesting broad utility of the anti-GM-CSF mechanism. Macrophages have been implicated in the progression of fibrosis in lung injury, which indicates a potential role of anti-GM-CSF as an antifibrotic. Numerous other cytokine inhibitors, including those targeting TNF-α, IL-6, IL-23, and IL-17, have been successfully clinically validated across a broad range of indications, which we believe suggests potentially broad and flexible application of namilumab. Targeting GM-CSF has been clinically validated in two other autoimmune diseases, rheumatoid arthritis and giant cell arteritis, where Phase 2 trials have shown anti-GM-CSFs to be generally well tolerated and to have demonstrated the potential for symptom resolution. Additionally, namilumab is being developed with potentially the least frequent dosing schedule of other subcutaneous anti-GM-CSFs in Phase 2 or Phase 3 clinical trials, with a single dose every four weeks after an initial loading period, and has been studied in approximately 300 patients to date. Based on the anti-GM-CSF development landscape, we believe that namilumab has potential for pulmonary sarcoidosis and multiple avenues for expansion across both clinically validated indications and indications with no known anti-GM-CSF development. The three other anti-GM-CSFs currently in Phase 2 or Phase 3 clinical trials are GlaxoSmithKline's otilimab, which is subcutaneous, dosed weekly, and currently undergoing Phase 3 trials in rheumatoid arthritis and a Phase 2 trial in COVID-19; Kiniksa's mavrilumab, which is subcutaneous, dosed every two weeks, and last completed a positive Phase 2 trial in giant cell arteritis and is undergoing a Phase 3 trial in COVID-19 pneumonia and hyperinflammation; and Humanigen's lenzilumab, which is intravenous, dosed every four weeks, and reported positive topline results in a Phase 3 trial in COVID-19 pneumonia.

Namilumab for the Treatment of Sarcoidosis

Sarcoidosis overview and limitations of current treatments

Sarcoidosis is a multi-organ autoimmune disease characterized by the presence of granulomas believed to form via an exaggerated immune response to unidentified antigens. Sarcoidosis primarily affects the lungs and

lymphatic system, though sarcoidosis may damage any organ. Granulomas are compact, centrally organized collections of macrophages and epithelioid cells encircled by lymphocytes and form during a normal immune response to trap foreign pathogens, restrict inflammation, and protect the surrounding tissue. The hallmark of sarcoidosis is the presence of CD4+ T cells that interact with antigen-presenting cells to initiate the formation, maintenance, and accumulation of granulomas.

Sarcoidosis affects approximately 200,000 patients in the United States alone and can present itself acutely or subacutely with lymph node enlargement, shortness of breath, dry cough, skin, joint or eye lesions, or abnormalities on chest x-ray or CT. Approximately 95% of sarcoidosis patients have lung involvement, and around 20 to 30% of patients develop permanent lung damage from the disease. An estimated 54% of pulmonary sarcoidosis patients are diagnosed, and approximately 90% of these patients receive some form of treatment. The annual incidence of sarcoidosis in African-Americans is threefold that of Caucasian Americans. Some studies report a slight predominance of sarcoidosis among females compared to males, while others show no gender predilection. Age at onset ranges from 20s to over the age of 50. Corticosteroids are the most widely used treatment for sarcoidosis, but they carry significant side effects when used longer-term, and relapses are common when attempting to taper. There are multiple second- and third-line treatment options, including immunosuppressive therapies such as methotrexate and azathioprine as well as biologics such as TNF inhibitors, but their use is limited by slow onset, safety risk, inconsistent effectiveness, and reimbursement challenges. There remains significant unmet medical need for patients who are not well-controlled by steroids or immunosuppressants (patients may remain symptomatic or may not be able to tolerate effective doses) that could be met by a novel biologic. Market research with HCPs and third-party analysis of claims data suggest that approximately 25% of diagnosed and treated pulmonary sarcoidosis would be eligible for treatment with second-line or later therapy.

The granulomatous response is believed to begin when an antigen chronically stimulates and activates antigen-presenting cells, including alveolar macrophages. Macrophages process and present the antigen, leading to the activation of CD4+ helper T cells, which form and maintain the granuloma by the production of pro-inflammatory cytokines such as TNF-α, GM-CSF, and IL-12 that in turn recruit inflammatory cells such as peripheral blood monocytes. The activated immune environment of the granuloma may lead to significant damage to the surrounding tissue, and the development of advanced fibrosis permanently alters organ structure and function.

GM-CSF, a key pathogenic cytokine, has been critically implicated in multiple parts of the granulomatous response. GM-CSF is involved in the activation and fusion of alveolar macrophages into multinucleated giant cells, the priming and maintenance of T cell activation and the interactions between lymphoid and myeloid cells that promote granuloma formation. Further, GM-CSF production appears to amplify cellular immunity mediated by helper T cells (Th1, Th2, and Th17) that are also believed to be critical during the granulomatous response and thereby driving the local immune response. In patients with sarcoidosis, GM-CSF has been shown to be increased in serum and broncho-alveolar fluid and correlated with disease activity.

Clinical data

In a Phase 1 study of healthy volunteers with a single subcutaneous injection, namliumab was observed to be generally well-tolerated. In a Phase 2 trial in patients with moderate to severe rheumatoid arthritis (RA) conducted by Takeda, namilumab demonstrated decreased disease activity compared to placebo. In this trial, patients were given a subcutaneous injection of either 20, 80, or 150 mg of namilumab four times over a ten-week period. Results showed a dose-dependent response to treatment, with a statistically significant difference for the 150 mg dose in the 28-joint Disease Activity Score, C-reactive protein version (DAS28-CRP), the primary endpoint, at week 12. Compared to placebo, namilumab also increased patients' ACR score, which measures RA signs and symptom improvement. Over the 12-week study period, 14 of 27 (52%) subjects receiving placebo and 45 of 81 (56%) receiving namilumab experienced a treatment-emergent adverse event (TEAE). The most common TEAEs, shown in the table below, were nasopharyngitis, dyspnea, bronchitis, and

headache. One serious adverse event, a myocardial infarction, was reported in the 150 mg arm. The patient, a 63-year old smoker, was withdrawn from the trial and recovered after cardiac catheterization. Although we believe namilumab has significant potential in RA, we believe we can deliver greater value to patients if we pursue development in sarcoidosis first, where the unmet medical need is greater.

Preferred term	Placebo (*N* = 27)	Namilumab 20 mg (*N* = 28)	Namilumab 80 mg (*N* = 25)	Namilumab 150 mg (*N* = 28)
Nasopharyngitis	5(18.5)	5(17.9)	1(4.0)	4(14.3)
Dyspnea	0	1(3.6)	2(8.0)	3(10.7)
Bronchitis	2(7.4)	1(3.6)	1(4.0)	1(3.6)
Headache	1(3.7)	1(3.6)	3(12.0)	0
Upper respiratory tract infection	0	0	2(8.0)	1(3.6)
Rheumatoid arthritis	0	2(7.1)	2(8.0)	0
Hypertension	0	0	0	2(7.1)
Laryngitis	0	0	2(8.0)	0
Menorrhagia	0	2(7.1)	0	0
Urticaria	0	2(7.1)	0	0

Values are *n* (%). *TEAE* treatment-emergent adverse event

Development plan

We plan to initiate a Phase 2 trial to test the safety and efficacy of namilumab in pulmonary sarcoidosis in the first half of calendar year 2022. We believe the anti-GM-CSF mechanism has potential for broad application due to the numerous disease functions of GM-CSF, giving the opportunity to expand autoimmune disease indications.

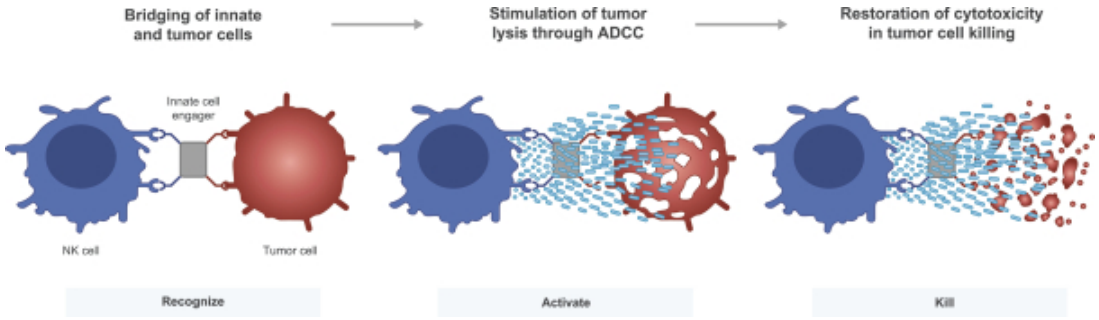
Affivant Overview

- **Overview:**
  - Affivant is focused on the future development and commercialization of AFM32 and other bispecific antibodies through its licensing and strategic collaboration agreement with Affimed to develop and commercialize novel innate cell engagers for multiple cancer targets.
- **Lead program:**
  - AFM32 is a preclinical immune-engaging bispecific antibody licensed from Affimed with potential applicability to several solid tumor indications.
- **Preclinical data:**
  - In a head-to-head preclinical study, AFM32's potency exceeded that of a monoclonal antibody ("mAb") that has been clinically validated against the same tumor target.
  - AFM32's potency also exceeded the potency of antibody-drug conjugate ("ADC") agents that have been clinically validated against the same tumor target, as reported in published preclinical studies.
- **Development plan and upcoming milestones:**
  - We expect to file an IND for AFM32 in the first half of calendar year 2023.
- **Roivant ownership:**
  - As of September 30, 2021, we own 100% of the issued and outstanding common shares of Affivant and 99% on a fully diluted basis.
- **Pipeline:**

Bispecific Innate Cell Engagers and Affimed's ROCK Platform

Bispecific innate cell engagers ("ICE") are a novel class of drugs that activate the innate immune system and trigger a concerted anti-tumoral immune response. These bispecific antibodies consist of tumor-associated antigen binding domains, which cause high affinity and high specificity binding to the tumor surface, and immune cell binding domains, which bind and activate specific immune cell subsets able to kill the tumor cell. The Fc region of the antibody links the two domains together and improves pharmaceutical properties. The cross-linking of tumor and immune cells acts as a bridge that increases their proximity and creates a spatial stimulus, enabling the immune cell to kill the tumor cell.

Affimed's Redirected Optimized Cell Killing ("ROCK") platform technology generates diverse, tetravalent, bispecific antibodies known as ICE, which can be customized to target specific binding domains on hematologic and solid tumor cells. The immune cell binding domain of ICE includes a high affinity CD16A-directed domain that binds to CD16A receptors on natural killer ("NK") cells with a unique epitope. CD16A is sufficient to fully activate cell killing by NK cells and macrophages, differentiating ICE from other platforms that can engage NK cells. In addition, there is no dilution or sink effect through neutrophils (CD16B+) as the molecules are highly selective for CD16A. These ICE antibodies are superior to mAbs and Fc-enhanced mAbs in their ability to bind with high affinity to CD16A with minimal serum IgG competition. The ROCK platform has generated clinical proof of concept through clinical trials of AFM13 in patients with peripheral T-cell lymphoma, where AFM13 was well-tolerated and demonstrated tumor shrinkage or slowing of tumor growth. Our goal is to develop CD16A NK antibodies with the potential for targeted immune activation and tumor destruction, along with a safety profile more like traditional antibody-based products.



AFM32

AFM32 is an ICE program currently in the preclinical stage of development. AFM32's Fc region is fused to two high affinity CD16A binding single chain variable regions to maximize NK cell and macrophage engagement. The biological target of AFM32's tumor-associated antigen binding domain has been clinically validated via other targeted agents (mAb and ADC), including both evidence of single agent activity and a generally well-tolerated safety profile of the corresponding mAb in published studies. We believe AFM32 has potential applicability across several highly prevalent solid tumor types, providing the optionality to pursue multiple large-market indications.

Preclinical data

In a head-to-head preclinical study, AFM32 potency, as measured by target cell killing, exceeded that of a mAb, and in preclinical studies, AFM32's potency exceeded the potency (as reported in published preclinical studies) of ADC agents that have been clinically validated against the same tumor target. Furthermore, based on preclinical and clinical experiences with other ICE antibodies in separate studies, we believe that the tolerability of AFM32 has the potential to be superior to that observed to date with antibody-drug conjugates in published literature.

Development plan

Pursuant to a collaboration and licensing agreement between Affivant and Affimed, Affimed is conducting a significant portion of the AFM32 preclinical work for the collaboration under the governance of a Joint Steering Committee controlled by Affivant. Pursuant to the agreement Affivant will be responsible for submitting any IND or equivalent for AFM32, and will be responsible for all future clinical development and commercialization worldwide, with Affimed retaining an option for co-promotion. We also have the option to license from Affimed additional ICE molecules directed against targets that are not (a) currently licensed or optioned to third parties or (b) directed against targets included in Affimed's current pipeline.

Cytovant Overview

- **Overview:**
  - Cytovant's mission is to discover, develop and commercialize cell therapies that are uniquely suited to Asian patients.
- **Lead program:**
  - *CVT-TCR-01:* TCR-T therapeutic targeting NY-ESO-1, an intracellular cancer testis antigen whose expression is nearly exclusive to malignant tissue, being developed in Asia for the treatment of soft tissue sarcoma and other tumors with high disease burden in the region.
- **Disease overview:**
  - NY-ESO-1 is expressed in many tumor types associated with substantial unmet need in Asia, including soft tissue sarcoma, ovarian cancer, esophageal cancer and lung cancer. In 2020, the estimated incidences of colorectal, lung and esophageal cancer in China were 38.4, 56.3 and 22.4 cases per 100,000 individuals; these tumors are associated with NY-ESO-1 positivity rates of 17%, 19% and 21%, respectively.
- **Limitations of current treatments:**
  - The current treatment options for soft tissue sarcoma leave significant unmet need, as chemotherapy for systemic treatment has an overall survival of approximately 12 months, and up to 40% of patients who receive surgery and radiotherapy eventually recur at distant sites.
- **Preclinical data:**
  - CVT-TCR-01 has demonstrated strong activity against NY-ESO-1-positive cell lines in preclinical experiments and has further demonstrated highly specific on-target activity by sparing cell lines that are NY-ESO-1-negative. Moreover, in preclinical experiments, CVT-TCR-01 has been shown to induce strong proinflammatory cytokine secretion upon exposure to NY-ESO-1 positive cell lines, further supporting its antitumor activity.
- **Roivant ownership:**
  - As of September 30, 2021, we own 72% of the issued and outstanding common shares of Cytovant and 68% on a fully diluted basis, in each case including both direct and indirect ownership in Cytovant.
- **Pipeline:**

Cytovant holds development and commercialization rights for Greater China (includes People's Republic of China, Hong Kong, Taiwan, and Macau), Japan, and the Republic of Korea.

TCR-T Background

As part of normal immune surveillance, the body identifies diseased cells through the T-cell receptor ("TCR"), which binds and recognizes the HLA peptide complex. The HLA peptide complex is comprised of short fragments of cellular proteins bound to HLA; this complex is then trafficked to the cell surface for presentation to T cells. When a T cell binds to a specific HLA peptide complex on a diseased cell, that cell is targeted for destruction. Importantly, peptide fragments that are bound to HLA are derived from intracellular, extracellular and transmembrane proteins, meaning that TCRs can target the entire array of cellular proteins. Notably, HLA types vary substantially across global populations, with markedly different HLA types commonly observed in Asian populations relative to Caucasian populations. For example, two high-frequency alleles in

Southern Chinese people, HLA-A*02:07 (20%) and HLA-A*02:03 (10%), are not addressed by any current TCR-based therapy. The ability of a specific TCR to bind and recognize an HLA peptide complex is limited to matched HLA types; thus, a TCR that recognizes an HLA peptide complex found in Caucasian patients may not recognize an HLA peptide complex found in Asian patients.

The ability of T cells to recognize and kill diseased cells via the TCR can be manipulated to target specific cells, including cancerous cells. This constitutes the basis of TCR-T therapeutics, in which affinity- or specificity-enhanced T cell receptors are genetically engineered into a patient's own T cells and then used as a direct anti-cancer treatment. This technology affords several advantages compared to other forms of adoptive cell therapy ("ACT"), including chimeric antigen receptor T-cells ("CAR-T"). Two key advantages include:

- **Greater range of target antigens**: Unlike CAR-T, which relies upon antibody fragment binding to cell surface proteins for cell recognition and destruction, TCR-T can recognize intracellular antigens as well. As most cancerous cells express cancer-specific intracellular antigens, this widens the range of addressable targets for TCR-T relative to CAR-T.
- **Specificity for malignant tissue**: To date, all approved CAR-T products are specific to targets expressed on both healthy and diseased tissue. By contrast, TCR-T targets can be specific exclusively or nearly exclusively to malignant tissue, potentially limiting off-target toxicities.

Because TCR-T therapeutics must be specific to both an antigen (which discriminates specific tumor types) and an HLA type (which discriminates specific addressable populations), we believe that Cytovant's focus on the unique medical needs of Asian patients will give the company an advantage relative to organizations that lack an explicit focus on Asian markets. Similarly, because of the complexity of cell therapy manufacturing as well as China's comprehensive regulatory regime regarding human tissue, we believe that Cytovant's local focus and the team's on-the-ground manufacturing experience represent a key competitive advantage over global competitors.

The cell therapy landscape in China is saturated with CAR-T treatments, primarily for hematologic oncology. Cytovant's TCR-T approach will face fewer TCR-T competitors and may better enable solid tumor targeting, a larger market opportunity than blood cancers.

Development-Stage Cellular Therapeutics in China

Antigen	CAR-T
BCMA	22
CD19	88
CD22	18
Total CAR-T	244
Total TCR-T	46

Clarivate Analytics as of January 2021

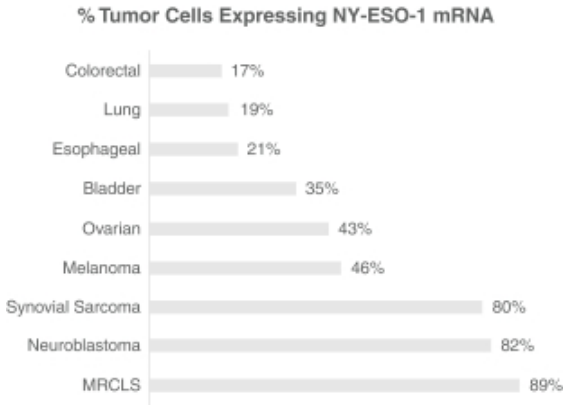
CVT-TCR-01

CVT-TCR-01 is a preclinical TCR-T therapeutic candidate being developed to target cancer testis antigen NY-ESO-1 presented by HLA-A*02. NY-ESO-1 has several characteristics that make it well-suited to ACT-based immunotherapeutic approaches. First, NY-ESO-1 is an oncofetal protein expressed primarily in malignant tissue; in particular, it is highly expressed in soft tissue sarcoma, ovarian cancer, esophageal cancer and lung cancer, among other common tumors. Second, NY-ESO-1 is highly immunogenic and its expression is associated with decreased survival. Finally, because NY-ESO-1 is expressed only intracellularly, we believe it is a suitable target for a TCR-T-based approach.

NY-ESO-1 positive cancers and limitations of current treatments

NY-ESO-1 positive cancers represent a substantial health burden in East Asia. The estimated incidences of colorectal, lung and esophageal cancer in China are 38.4, 56.3 and 22.4 cases per 100,000 individuals; these tumors are associated with NY-ESO-1 positivity rates of 17%, 19% and 21%, respectively. Among certain less common tumors, NY-ESO-1 positivity increases significantly, with 35% of bladder cancers, 43% of ovarian cancers and more than 80% of soft tissue sarcomas expressing the antigen. The estimated incidences of these tumor types in China are 5.9, 7.8 and 3.2 cases per 100,000 individuals. In aggregate, these six tumor types represent a prevalent population of more than 3,000,000 patients in China alone, of which we estimate more than 600,000 are likely to be NY-ESO-1 positive.

NY-ESO-1 is Highly Expressed Across Many Fatal Cancers in Asia

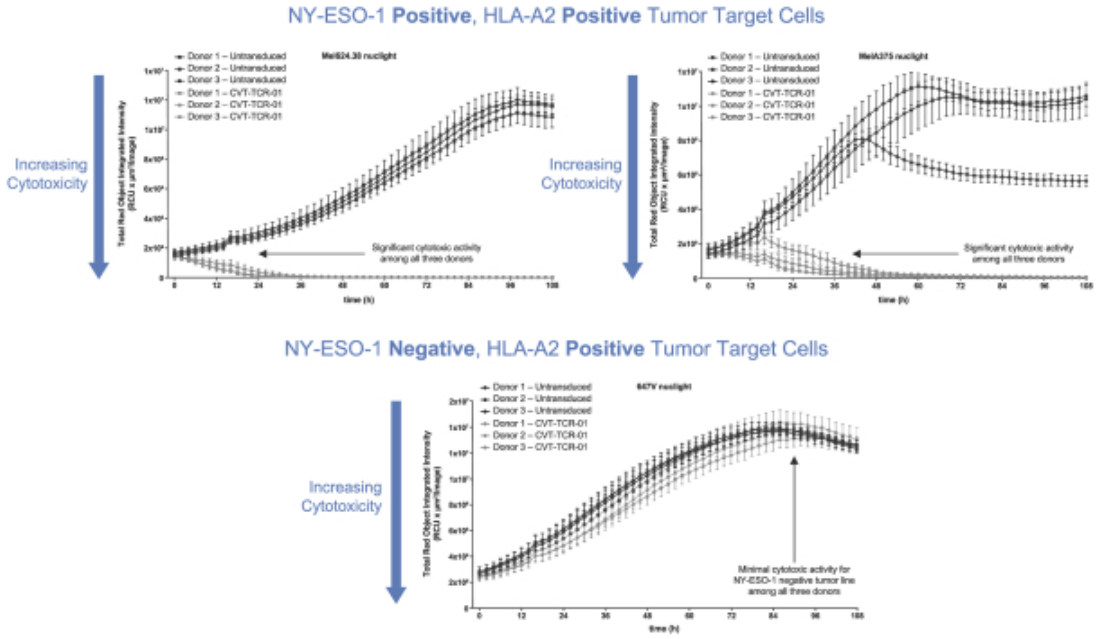


While local control of soft tissue sarcoma is achievable through surgery and radiotherapy, up to 40% of patients eventually recur at distant sites, of whom over 90% ultimately die of this malignancy. For patients with locally advanced or metastatic sarcoma, conventional chemotherapy with doxorubicin and/or ifosfamide used sequentially or in combination represents the backbone of systemic treatment, for which overall survival is approximately 12 months. The high mortality and limited development of novel treatment options leaves significant unmet need for patients suffering from soft tissue sarcoma.

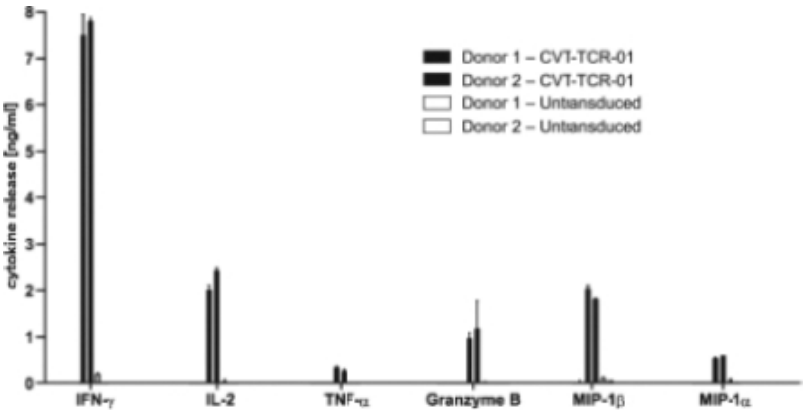
Preclinical data

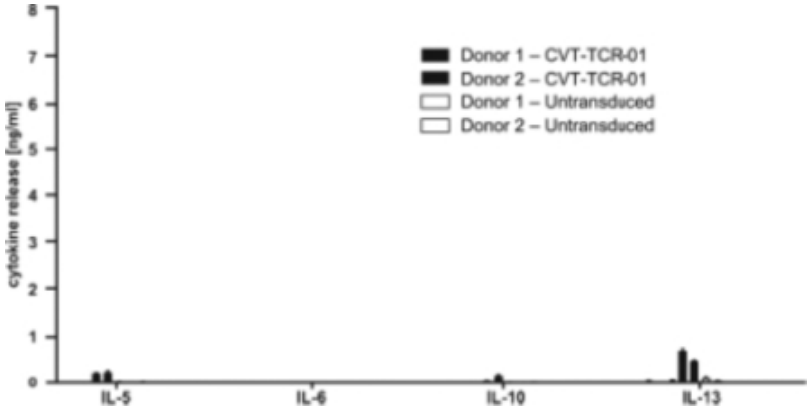
In preclinical testing, CVT-TCR-01 demonstrated specific and potent killing of NY-ESO-1-positive cell lines as assessed by IFN-g release. Moreover, CVT-TCR-01 was shown to spare NY-ESO-1 negative cell lines, indicating the candidate's specificity for NY-ESO-1. In subsequent cytotoxicity assays, CVT-TCR-01's activity was shown to be dependent on both NY-ESO-1 and HLA-A2 expression, consistent with CVT-TCR-01's specificity for NY-ESO-1 presented by HLA-A2. Finally, cytokine release assays indicated that CVT-TCR-01 induces strongly proinflammatory Th1-type cytokine secretion upon exposure to NY-ESO-1 positive cell lines, further supporting CVT-TCR-01's antitumor activity. Additionally, preliminary clinical results from NY-ESO-1 directed TCR therapy demonstrate promising overall response rates in a wide variety of tumor types, including synovial sarcoma, multiple myeloma and myxoid round cell liposarcoma.

CVT-TCR-01 Shows Comparable Cytotoxic Activity in Three Donors



CVT-TCR-01 Transduced Effector Cells Secrete Th1-Type Cytokines





There are multiple competing cellular therapeutics targeting NY-ESO-1 in development both globally and in Asia specifically. Among global programs, the most advanced is letetresgene autoleucel, which GlaxoSmithKline is currently developing in multiple solid tumor types in several Phase 1 and 2 studies. Prior studies of letetresgene autoleucel demonstrated strong antitumor activity in patients with NY-ESO-1-positive soft tissue sarcoma, in which overall response rates of up to 50% were observed. Among Asia- and China-specific programs, competing NY-ESO-1-targeting TCR-Ts include TAEST-16001, which is being developed by Xiangxue Life Sciences; TBI-1301, which is being developed by Takara Bio and Otsuka Pharmaceutical Co.; and a program in development by Shenzhen Binde Bio.

Arbutus Overview

- **Overview:**
  - Arbutus Biopharma Corporation is a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of wholly-owned assets with different mechanisms of action to provide a cure for people with chronic hepatitis B virus (HBV) infection and to treat coronaviruses (including COVID-19).
- **Lead programs:**
  - *AB-729:* Subcutaneously-delivered RNAi therapeutic targeted to hepatocytes using Arbutus's proprietary covalently conjugated GalNAc delivery technology that inhibits viral replication.
  - *AB-836:* Proprietary third-generation oral capsid inhibitor that suppresses HBV DNA replication.
- **Disease overview:**
  - Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.
- **Limitations of current treatments:**
  - Current treatment options include nucleos(t)ide analogs ("NA") and pegylated interferon regimens. However, fewer than 5% of patients are functionally cured by these current treatment options after a finite treatment duration. With such low cure rates, most patients with chronic HBV infection are required to take NA therapy daily for the rest of their lives.
- **Clinical data:**
  - Preliminary data from ongoing single- and multi-dose Phase 1a/1b clinical trials for AB-729 demonstrate robust hepatitis B surface antigen (HBsAg) reductions in multiple patient cohorts. AB-729 has been observed to be well-tolerated after single and repeat doses based on results to date. These data support dosing intervals of up to 12 weeks.
  - Repeat dosing of AB-729 60 mg every 8 weeks results in comparable mean HBsAg declines relative to 60 mg every 4 weeks at week 44 (-1.88 log10 IU/mL vs -1.81 log10 IU/mL, p=0.8). The mean HBsAg decline for repeat dosing of AB-729 90 mg every 12 weeks at week 44 was -1.86 log10 IU/mL.
  - In HBV DNA positive chronic hepatitis B subjects, a single 90 mg AB-729 dose resulted in robust mean HBsAg (-1.02 log10 IU/mL) and HBV DNA (-1.53 log10 IU/mL) declines at week 12, as well as decreases in HBV RNA and core-related antigen.
  - Preliminary data from ongoing Phase 1a/1b clinical trial for AB-836 demonstrate that AB-836 is generally well-tolerated in both healthy subjects and patients with chronic HBV and provides robust antiviral activity.
- **Development plan and upcoming milestones:**
  - Arbutus initiated a Phase 2 clinical trial of a triple combination of AB-729, Assembly Biosciences' vebicorvir, and an NA in February 2021, with initial data expected in 2022.
  - Arbutus announced plans to evaluate a triple combination of AB-729, Antios Therapeutics's proprietary active site polymerase inhibitor nucleuotide ATI-2173, and Viread (tenofovir disoproxil fumarate) in a single cohort in the ongoing Antios Phase 2a ANTT201 clinical trial. The multi-center, double-blind, placebo-controlled, multiple-dose cohort will evaluate the safety, pharmacokinetics, immunogenicity, and antiviral activity of this triple combination. The cohort initiated in the fourth quarter of 2021.

- Arbutus expects to initiate a Phase 2a trial evaluating a triple combination of AB-729, Vaccitech's VTP-300, an immunotherapeutic designed to elicit an HBV specific immune response, and an NA compared to the double combination of AB-729, VTP-200 sham and an NA in subjects with chronic HBV infection in early calendar year 2022.
- Arbutus received authorization from the FDA to proceed with its IND application for AB-729 in a Phase 2a clinical trial. The Phase 2a proof-of-concept clinical trial , which has begun dosing patients, will evaluate the safety and efficacy of AB-729 in combination with ongoing NA therapy and short courses of Peg-IFN-2a in subjects with chronic HBV infection.
- Arbutus is continuing to enroll and dose chronic HBV patients in Part 3 of its ongoing AB-836 Phase 1a/1b clinical trial and anticipates presenting additional data at a medical conference in 2022.

- Roivant ownership:
  - As of September 30, 2021, we own 29% of the issued and outstanding common shares of Arbutus and 27% on a fully diluted basis, in each case including the conversion of preferred shares held by Roivant into common shares, which was completed on October 18, 2021.

Sio Gene Therapies Overview

- **Overview:**
  - Sio Gene Therapies is a clinical-stage company focused on developing gene therapies for neurodegenerative diseases, with a pipeline of innovative product candidates for the treatment of GM1 gangliosidosis, GM2 gangliosidosis (including Tay-Sachs disease and Sandhoff disease) and Parkinson's disease.
- **Lead programs:**
  - *AXO-AAV-GM1:* Investigational gene therapy currently being developed as a potential one-time disease modifying treatment for GM1 gangliosidosis, a rare disease caused by loss-of-function mutations in the GLB1 gene. The program utilizes an adeno-associated virus (AAV) vector to deliver a functional copy of the GLB1 gene with the goals of restoring ß -gal enzyme activity in the CNS and reducing GM1 ganglioside accumulation, to ultimately improve neurological function and extend survival.
  - *AXO-AAV-GM2:* Investigational gene therapy currently being developed as a potential one-time disease modifying treatment for GM2 gangliosidosis (including Tay-Sachs disease and Sandhoff disease). The AXO-AAV-GM2 program utilizes AAV dual vectors to deliver functional copies of both the HEXA gene and the HEXB gene, with the goal of restoring normal Hex A enzyme function in the central nervous system.
  - *AXO-Lenti-PD: In vivo* lentiviral gene therapy investigational product candidate currently being developed as a potential one-time treatment of Parkinson's disease. AXO-Lenti-PD delivers a construct of three genes that encode the critical enzymes required for the biochemical synthesis of dopamine from endogenous tyrosine.
- **Disease overview:**
  - GM1 gangliosidosis is a rare, inherited neurodegenerative lysosomal storage disorder characterized by the accumulation of GM1 ganglioside with an estimated incidence of approximately one in 100,000 live births worldwide.
  - GM2 gangliosidosis, also known as Tay-Sachs or Sandhoff diseases, is a rare, inherited neurodegenerative lysosomal storage disorder characterized by buildup of GM2 ganglioside in lysosomes with an estimated incidence of approximately one in 150,000 live births worldwide.
  - Parkinson's disease is a chronic neurodegenerative disorder that primarily results in progressive and debilitating motor symptoms. It is estimated that up to 1 million people in the U.S. and 7 to 10 million people worldwide suffer from Parkinson's disease.
- **Limitations of current treatments:**
  - *AXO-AAV-GM1:* GM1 gangliosidosis is uniformly fatal, and there are no disease-modifying treatment options. Management is limited to symptomatic treatment and palliative care.
  - *AXO-AAV-GM2:* There are no disease-modifying treatment options for either Tay-Sachs disease or Sandhoff disease, and management is limited to symptomatic treatment and palliative care.
  - *AXO-Lenti-PD:* The treatment of Parkinson's disease is limited to symptomatic treatments, as no therapies have proven effective in altering the course of the disease or addressing the underlying pathophysiological processes. One-time gene therapy has the potential to reduce reliance on levodopa-based therapies, reduce troublesome side effects such as dyskinesia, and slow the course of disease progression.
- **Clinical data:**
  - *AXO-AAV-GM1:* Data from the ongoing Phase 1/2 trial have shown AXO-AAV-GM1 to be generally well-tolerated, with a dose-dependent improvement in key biomarkers of disease activity and no overt

disease progression in six out of seven patients treated across the low- and high-dose cohorts. At six months, in both patients in the high dose cohort, serum Î²-galactosidase activity achieved a normal range, increasing by 12x and 17x pre-treatment levels, respectively, and levels of GM1 ganglioside were normalized with 42% and 72% reductions, respectively. A total of ten patients have received AXO-AAV-GM1 to date, with no SAEs attributable to AXO-AAV-GM1.

- *AXO-AAV-GM2:* Clinically meaningful improvement in motor skills and disease stabilization were observed in two infants with Tay-Sachs disease following administration under expanded access protocol. An IND was cleared by FDA in November 2020 and three patients have been dosed to date.
- *AXO-Lenti-PD:* Preliminary data from ongoing Phase 2 trial have shown AXO-Lenti-PD to be generally well-tolerated and to demonstrate dose-dependent improvements in motor function. To date, 21 patients have received gene therapy in dose-escalation studies spanning 5 dose cohorts.

- **Development plan and upcoming milestones:**
  - *AXO-AAV-GM1:* Sio expects to provide a data update from Stage 1 of its ongoing Phase 1/2 trial, including both Type 1 and Type II patients, in the first half of calendar year 2022.
  - *AXO-AAV-GM2:* Sio expects to continue patient identification, screening and enrollment in Stage 1 of its ongoing Phase 1/2 trial throughout 2021.
  - *AXO-Lenti-PD:* Sio expects to complete Qualified Person certification of clinical trial material in the fourth quarter of 2021 and to provide a program update in the first quarter of 2022.
- **Roivant ownership:**
  - As of September 30, 2021, we own 25% of the issued and outstanding shares of Sio common stock and 24% on a fully diluted basis.

Asset Acquisition and License Agreements; Other Vant Agreements

Immunovant

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, our wholly owned subsidiary, Roivant Sciences GmbH (“RSG”), entered into a license agreement with HanAll Biopharma Co., Ltd. (“HanAll”) (the “HanAll Agreement”). Under the HanAll Agreement, RSG received (i) the non-exclusive right to manufacture and (ii) the exclusive, royalty-bearing right to develop, import and use the antibody referred to as IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States, Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America (the “HanAll Licensed Territory”), for all human and animal uses. RSG also received the right to grant a sublicense, with prior written notice to HanAll of such sublicense, to: (i) a third party in any country in the HanAll Licensed Territory outside of the United States and E.U.; (ii) an affiliate of RSG in any country in the HanAll Licensed Territory; and (iii) a third party in the United States and E.U. only after submission of a biologics license application in the United States or a Marketing Authorization Application in the E.U. Pursuant to the HanAll Agreement, RSG granted to HanAll an exclusive, royalty-free license under certain RSG patents, know-how and other intellectual property relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the HanAll Licensed Territory.

In December 2018, Immunovant Sciences GmbH, (“ISG”) obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 in the HanAll Licensed Territory, for an aggregate purchase price of $37.8 million plus Swiss value-added tax of $2.9 million. HanAll and RSG have agreed that neither they nor certain of their affiliates will clinically develop or commercialize certain competitive products in the HanAll Licensed Territory.

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. ISG is obligated to reimburse HanAll for half of such research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of $20.0 million.

Pursuant to the HanAll Agreement, RSG made an upfront payment of $30.0 million to HanAll in December 2017. In May 2019, ISG achieved its first development and regulatory milestone, which resulted in a $10.0 million milestone payment that ISG subsequently paid to HanAll in August 2019. ISG will be responsible for future contingent payments and royalties, including up to a maximum of $442.5 million upon the achievement of certain development, regulatory and sales milestone events. ISG is also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens on net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of (i) the date on which the last valid claim of the licensed patents that cover such licensed product in such country expires, (ii) the date on which the data or market exclusivity for such licensed product in such country expires or (iii) 11 years after the first commercial sale of such licensed product in such country. The HanAll Agreement will expire on a product-by-product basis on the expiration of the last royalty term with respect to a given licensed product, unless earlier terminated. ISG may terminate the HanAll Agreement in its entirety without cause upon 180 days' written notice following 30 days of discussion. Either party may terminate the HanAll Agreement upon 60 days' written notice for uncured material breach (or 30 days in the case of non-payment), or immediately upon written notice if the other party files a voluntary petition, is subject to a substantiated involuntary petition or for certain other solvency events. HanAll may terminate the HanAll Agreement if ISG or its affiliates challenge the validity or enforceability of any of the licensed patents.

Proteovant

Michigan Research Agreement

In January 2018, our subsidiary Oncopia entered into a research agreement with the Regents of the University of Michigan (the "University of Michigan") (the "Michigan Research Agreement"). Pursuant to the Michigan Research Agreement, Oncopia and the University of Michigan are collaborating to discover and optimize small molecule protein degraders. Any intellectual property developed under the Michigan Research Agreement that is directed to certain targets will be licensed by the University of Michigan to Oncopia pursuant to the Michigan License Agreement, as described below. Pursuant to the Michigan Research Agreement, Oncopia is obligated to provide a low eight-digit amount in funding between 2021 and 2023. Unless earlier terminated based on customary termination rights or extended by mutual agreement, the Research Agreement continues until December 2023.

Michigan License Agreement

In November 2020, Oncopia entered into an amended and restated patent license agreement with the University of Michigan (the "Michigan License Agreement"), pursuant to which the University of Michigan granted Oncopia an exclusive, worldwide, sublicensable license under certain patents related to certain existing small molecule protein degraders and certain future small molecule protein degraders that may be developed under the Michigan Research Agreement to make, use and commercialize certain products covered by such patents. Such license grant is subject to, among other things, certain rights required to be granted under prior research or sponsorship agreements.

Under the Michigan License Agreement, Oncopia is obligated to pay the University of Michigan a low-to-mid single-digit royalty on net sales of each licensed product. Oncopia's royalty obligations apply on product-by-product, country-by-country basis and end upon the expiration of the last-to-expire valid claim of the licensed patents under the University of Michigan Agreement which covers such licensed product in such country. The patents and pending patent applications, if granted, currently licensed under the Michigan License

Agreement are expected to expire as early as 2037, and as late as 2042, without giving effect to any potential patent term extensions or patent term adjustments. Oncopia is obligated to pay the University of Michigan minimum annual royalties in the low five-digit range from March 2021 until the first commercial sale of a licensed product, at which time such minimum annual royalties will increase to a low six-digit amount. Oncopia may also be obligated to pay up to a maximum of a high seven-digit amount in development and commercial milestone payments on a per product basis. Unless earlier terminated based on customary termination rights, the term of the Michigan License Agreement will continue until the expiration of the last-to-expire valid claim of the licensed patents.

Dermavant

Agreements Relating to Tapinarof

In July 2018, our subsidiary Dermavant Sciences GmbH ("DSG") acquired the worldwide rights (other than for China) with respect to certain intellectual property rights retained by Welichem Biotech Inc. ("Welichem") to tapinarof and related compounds from Glaxo Group Limited and GlaxoSmithKline Intellectual Property Development Ltd. (collectively, "GSK") pursuant to an asset purchase agreement (the "GSK Agreement"). GSK previously acquired rights to a predecessor formulation of tapinarof from Welichem pursuant to an asset purchase agreement between GSK and Welichem entered into in May 2012 (the "Welichem Agreement"). Under the GSK Agreement, DSG made an upfront payment of £150.0 million (approximately $191 million) to GSK.

DSG is also obligated to pay GSK £100.0 million (approximately $133 million) within 70 days following the receipt of marketing approval of tapinarof in the United States. The GSK Agreement does not require DSG to pay any royalties on sales of tapinarof following commercialization or make any commercial milestone payments, except for milestones owed to Welichem as described below.

In addition, under the GSK Agreement, DSG assumed all obligations under the Welichem Agreement, including payment of up to C$80.0 million (approximately $61 million) in potential development milestone payments and up to C$100.0 million (approximately $76 million) in potential commercial milestone payments. Following the commencement of the two pivotal Phase 3 clinical trials of tapinarof for the treatment of psoriasis in May 2019, on June 5, 2019, DSG paid to Welichem a milestone payment of C$30.0 million (approximately $23 million). In the future DSG may seek to enter into a royalty financing or similar transaction to fund its milestone payments.

In August 2018, in connection with the GSK Agreement, DSG and GlaxoSmithKline Trading Services Limited ("GSK Trading") entered into a clinical manufacturing and supply agreement for tapinarof pursuant to which DSG obtained an existing supply of tapinarof drug product and drug substance as well as additional supply of tapinarof drug product for clinical trials on a cost plus basis. As required under the GSK Agreement, in April 2019, DSG and GSK Trading also entered into a commercial manufacturing and supply agreement (the "Commercial Supply Agreement") pursuant to which DSG will obtain tapinarof drug product and drug substance from GSK Trading. Under the Commercial Supply Agreement, GSK Trading will provide development services to prepare for the manufacture and supply of tapinarof at commercial scale. DSG will obtain commercial supply of tapinarof on a cost plus basis under the commercial supply agreement. As required under the GSK Agreement, DSG entered into a letter agreement with GSK whereby GSK has agreed to make certain planned capital improvements, including design work, the purchase and modification of additional equipment items, and the reconfiguration of the existing production modules at GSK's manufacturing site in Cork, Ireland with DSG agreeing to reimburse GSK an anticipated aggregate capital expenditure amount, which is not expected to exceed approximately €11.4 million (approximately $13 million). DSG is not required to reimburse GSK for any actual amounts incurred in excess of 110% of the anticipated aggregate capital expenditure amount and the letter agreement will terminate at the later of (i) the completion of the Planned Capital Improvements and (ii) reimbursement by DSG of GSK's actual capital expenditures related to such planned capital improvements.

Collaboration and License Agreement with Japan Tobacco Inc.

In January 2020, DSG entered into a collaboration and license agreement with Japan Tobacco Inc. ("Japan Tobacco") (the "Japan Tobacco Agreement"). Pursuant to the Japan Tobacco Agreement, DSG granted Japan Tobacco exclusive rights to develop, register and market tapinarof in Japan for the treatment of dermatological diseases and conditions, including psoriasis and atopic dermatitis. In connection with the Japan Tobacco Agreement, Japan Tobacco has signed an exclusive license with its subsidiary, Torii, for co-development and commercialization of tapinarof in Japan.

Under the Japan Tobacco Agreement, in January 2020, DSG received an upfront payment of $60.0 million and may receive up to an additional $53.0 million upon the achievement of certain development milestones for tapinarof in psoriasis and atopic dermatitis. In addition, DSG will be entitled to tiered purchase prices specified in the Japan Tobacco Agreement in consideration of DSG's commercial supply of tapinarof to Japan Tobacco under the terms of a separate commercial supply agreement to be negotiated by the parties. DSG also has the right to receive royalties, to be negotiated by the parties and consistent with the purchase prices, based on product sales of tapinarof in the indications to the extent that DSG is no longer responsible for supplying tapinarof to Japan Tobacco.

The Japan Tobacco Agreement will remain in effect until expiration of the obligation to pay royalties, unless terminated in accordance with the following: (1) for any reason by Japan Tobacco upon written notice to DSG, which notice must be provided (x) at least 90 days in advance, if the termination is prior to regulatory approval of tapinarof in Japan for any dermatological disease or condition, and (y) at least 180 days in advance, if the termination is subsequent to regulatory approval of tapinarof in Japan for any dermatological disease or condition; (2) by either party upon written notice for the other party's material breach if such party fails to cure such breach within the specified cure period; or (3) by DSG if Japan Tobacco or its affiliates or sublicenses participate in a challenge to certain of our patents.

Dermavant Financing Agreements—Dermavant Revenue Interest Purchase and Sale Agreement

In May 2021, DSG, as seller, entered into a Revenue Interest Purchase and Sale Agreement (the "RIPSA") with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P. (collectively, the "Purchasers"), together with U.S. Bank National Association, as collateral agent.

Following satisfaction of the funding conditions set forth in the RIPSA, including receipt of marketing approval from the FDA for tapinarof, the Purchasers are obligated to pay DSG a total of $160.0 million in accordance with the terms and conditions set forth in the RIPSA (the "Purchase Price"). In consideration therefor, each of the Purchasers will have the right to receive a low single-digit to high single-digit tiered percentage of quarterly revenues based on the achievement of specified net sales thresholds for tapinarof in the U.S., up to a cap set at a multiple of the Purchase Price paid to DSG by the Purchasers. Payments of such quarterly revenues to the Purchasers under the RIPSA are secured by a security interest in certain tapinarof-related assets, including intellectual property rights and certain other assets that are owned by, licensed to or otherwise controlled by DSG related to the development and commercialization of tapinarof.

The RIPSA contains certain representations and warranties and covenants applicable to DSL and its subsidiaries. The RIPSA also contains certain Events of Default (as defined in the RIPSA) such as the breach of payment and other obligations, bankruptcy-related events and cross-defaults with respect to other related documents and agreements creating indebtedness. The occurrence of an Event of Default following the Purchasers' funding of the Purchase Price triggers DSG's obligation to pay an Event of Default Fee (as defined in the RIPSA) of $160.0 million, less revenue payments previously paid, as liquidated damages. In addition, the occurrence of a change of control of DSG prior to the Purchasers funding the Purchase Price triggers DSG's right, but not the obligation, to terminate the RIPSA by payment of the Pre-Funding Change of Control Option Price (as defined in the RIPSA) to all of the Purchasers, which varies based on the date of termination and certain milestones with respect to tapinarof.

Dermavant Financing Agreements—Dermavant Credit Agreement with XYQ Luxco

In May 2021, our subsidiaries Dermavant Sciences Ltd. ("DSL"), Dermavant Holdings Limited, Dermavant Sciences IRL Limited and DSG, as borrowers (the "Borrowers"), and certain other subsidiaries of DSL, as initial guarantors, entered into a credit agreement (the "Credit Agreement") with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent. The Credit Agreement provides for a term loan of $40.0 million (the "Term Loan"), the proceeds of which were used by the Borrowers to repay in full and terminate an existing credit facility with Hercules Capital Inc., with the remaining proceeds to be used for working capital and other general corporate purposes.

The Term Loan bears interest at a fixed interest rate of 10.0% per annum, with interest paid quarterly in arrears until maturity in May 2026, at which time the principal amount is due. The Borrowers have the option to prepay the Term Loan in whole or in part, subject to (i) until May 2023, a prepayment premium of 5.0% of the principal amount being repaid (plus the present value of all future scheduled interest on the principal being prepaid that would accrue through May 2023 calculated based on a discount rate equal to the treasury rate plus 100 basis points, except in the event the prepayment is due to a change of control), (ii) from May 2023 to May 2024, a prepayment premium of 5.0% of the principal amount being repaid, and (iii) from May 2024 to May 2025, a prepayment premium of 2.5% of the principal amount being repaid. From May 2025 through maturity, the Term Loan may be prepaid in whole or part without a prepayment premium. Optional and mandatory prepayment of the Term Loan, as well as other forms of prepayment, repayment, applications or reductions, will also require that DSL pays an Exit Fee (as defined in the Credit Agreement), calculated based on the amount so prepaid, repaid, applied or reduced.

The Borrowers' obligations under the Credit Agreement are unconditionally guaranteed by the initial guarantors and secured by first priority security interests in substantially all of the tangible and intangible assets of the Borrowers and guarantors, including certain intellectual property rights, bank accounts, any and all insurance receivables, intercompany receivables and/or trade receivables and certain quotas and/or participation rights.

The Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings, including a covenant against the occurrence of a "change in control" (subject to the Borrowers' right to prepay the Term Loan), financial reporting obligations and certain limitations on indebtedness, liens (including on intellectual property and other assets), investments, distributions (including dividends), collateral, transfers, mergers or acquisitions, taxes, corporate changes and deposit accounts.

The Credit Agreement contains a minimum cash covenant that requires the initial Borrowers and the guarantors thereunder to maintain a minimum cash balance of $10.0 million until the earlier of (a) a Qualified IPO (as defined in the Credit Agreement), (b) an Ultimate Parent Spinout (as defined in the Credit Agreement), and (c) the date that XYQ Luxco, in its capacity as a purchaser under the RIPSA, has received cumulative payments from DSG under the RIPSA in an aggregate amount equal to its pro rata portion of the funding amount thereunder. The Credit Agreement also contains customary events of default (subject, in certain instances, to specified grace periods) including, but not limited to, the failure to make payments of interest, premium, fees, indemnity or principal under the Term Loan, the failure to comply with certain covenants and agreements specified in the Credit Agreement, defaults in respect of certain other indebtedness and certain events relating to bankruptcy or insolvency. If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Term Loan may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 2% per year may be applied to the outstanding principal balance, and the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Credit Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Credit Agreement would automatically become due and payable.

On the closing date of the Term Loan and in accordance with the Credit Agreement, DSL issued to XYQ Luxco a warrant to purchase an aggregate of 1,199,072 common shares of DSL. The warrant is exercisable at any time until the earlier of (x) seven years from the date of issuance and (y) three years from the closing of an underwritten initial public offering of DSL's common shares pursuant to an effective registration statement. The warrant includes customary registration rights and customary anti-dilution provisions for the common shares underlying the warrant in respect of certain corporate events (including share splits, share combinations, share dividends and other recapitalization transactions).

Genevant

Cross-License Agreement with Arbutus Biopharma Corporation

In April 2018, our subsidiary, Genevant Sciences Ltd. (together with its subsidiaries, "Genevant"), entered into a cross-license agreement with our affiliate, Arbutus Biopharma Corporation ("Arbutus"), which the parties amended twice in June 2018 (as amended, the "Arbutus Cross-License Agreement"). Pursuant to the Arbutus Cross-License Agreement Arbutus granted Genevant an exclusive, sublicensable, worldwide, transferable, irrevocable and perpetual license under certain patents and know-how relating to Arbutus's lipid nanoparticle and GaINAc technology for RNA-based applications other than hepatitis B virus ("HBV"), and certain other excluded fields. The license is subject to certain rights which have previously licensed by Arbutus to other third parties. Under the Arbutus Cross-License Agreement, Genevant granted back to Arbutus an exclusive, sublicensable, worldwide, irrevocable, perpetual, royalty-free license under the intellectual property licensed under the Arbutus Cross-License Agreement and certain intellectual property acquired by Genevant after the effective date of the Arbutus Cross-License Agreement for applications involving the treatment and prevention of HBV.

Genevant is obligated to pay Arbutus tiered low single-digit percentage royalties on sales of products covered by the licensed patents. If Genevant sublicenses intellectual property licensed from Arbutus or collaborates with any third party to develop, manufacture or commercialize any products covered by the intellectual property licensed by Arbutus, it will be required to pay Arbutus the lesser of (i) up to 20% of the Royalty-Related Receipts (as defined in the Arbutus Cross-License Agreement) received by Genevant from such sublicensees or collaborators and (ii) tiered low single-digit royalties on net sales by sublicensees. Genevant's royalty obligations apply on product-by-product, country-by-country basis and end on the date on which the last valid claim of the licensed patents in such country that covers such licensed product expires. The patents and pending patent applications, if granted, currently licensed under the Arbutus Cross-License Agreement are expected to expire as early as 2023, and as late as 2039, without giving effect to any potential patent term extensions or patent term adjustments. Unless earlier terminated based on customary termination rights, the Arbutus Cross-License Agreement will continue until the expiration of Genevant's royalty obligations.

In December 2021, Arbutus and Genevant Sciences GmbH, as an assignee of Genevant, entered into the third amendment (the "Amendment") to the Arbutus Cross License Agreement, which, among other things, clarified the treatment of proceeds received by Genevant from an action for infringement by any third parties of Arbutus's intellectual property licensed to Genevant. In such an infringement action, Arbutus would be entitled to receive, after deduction of litigation costs, 20% of the proceeds received by Genevant or, if less, tiered low single-digit royalties on net sales of the infringing product (inclusive of the proceeds from litigation or settlement, which would be treated as net sales). The Amendment also clarified that, if a third party sublicensee of intellectual property licensed by Genevant from Arbutus commercializes a sublicensed product, Arbutus becomes entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other salesrelated revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

Aruvant

License Agreement with Cincinnati Children's Hospital Medical Center

In November 2018, our subsidiary Aruvant Sciences Ltd. ("Aruvant"), through its wholly owned subsidiary Aruvant Sciences GmbH ("ASG"), entered into a license agreement with Cincinnati Children's Hospital Medical Center ("CCHMC"), pursuant to which CCHMC granted ASG (i) an exclusive, royalty-bearing, worldwide license for the use of certain patents, know-how and data relating to certain gene therapies for sickle cell anemia and certain other hemoglobinopathies, including ARU-1801, and for related manufacturing processes, and (ii) a non-exclusive, royalty-bearing, worldwide license for the use of relevant future CCHMC's patents and general manufacturing know-how (the "CCHMC License Agreement"). The license is subject to, among other things, a non-exclusive license previously granted by CCHMC to another party.

In consideration for entering into the CCHMC License Agreement, Aruvant issued nine million common shares to CCHMC. Aruvant is obligated to issue additional shares to CCHMC upon the earliest of (i) immediately prior to a change of control event, (ii) immediately following Aruvant's issuance, in the aggregate, of equity securities, convertible or exchangeable securities, or other securities in exchange for cash equal to or in excess of $150.0 million or (iii) immediately prior to the effectiveness of a registration statement in connection with an initial public offering by Aruvant. When such a triggering event occurs, Aruvant must issue CCHMC additional shares equal to the difference between 12% of Aruvant's fully diluted share capital, less the closing shares.

ASG has paid CCHMC approximately $25.0 million in upfront licensing fees and is obligated to pay up to $30.0 million in the aggregate in sales, development and regulatory milestones for the first licensed product to reach certain specified milestones. Additionally, ASG is obligated to pay to CCHMC a low to mid single-digit royalty on net sales of licensed products subject to certain potential downward adjustments for third-party licenses, expiration of certain patent claims or the entry into the market of a competing generic product. ASG's royalty obligations continue on product-by-product and country-by-country basis until the latest to occur of (i) the date on which the last valid claim of the licensed patents covering such licensed product in such country expires, (ii) the ten-year anniversary of the first commercial sale of such licensed product in such country or (iii) the expiration of regulatory exclusivity for such licensed product in such country. Unless earlier terminated based on customary termination rights, the CCHMC License Agreement will continue on a product-by-product basis until the expiration of the royalty term for such licensed product. In the event of termination, the license granted to ASG under the agreement will terminate and, in the case of ASG's termination for convenience or CCHMC termination for ASG's material breach or bankruptcy, ASG will be deemed to grant CCHMC a non-exclusive, worldwide, perpetual license under ASG's patents and know-how that relate to the licensed products and any patents for jointly developed inventions to develop and commercialize any product. Such license is royalty-free in the case of termination for ASG's material breach or bankruptcy, and will be royalty-bearing on terms to be negotiated in good faith in the case of termination by ASG for convenience.

Lysovant

License Agreement with iNtRON Biotechnology, Inc.

In November 2018, our subsidiary, Lysovant Sciences GmbH ("LSG"), entered into a license agreement with iNtRON Biotechnology, Inc. ("iNtRON"), which the parties amended in March 2019 and August 2019 (the "iNtRON License Agreement"). Pursuant to the iNtRON License Agreement, iNtRON granted LSG an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and know-how to develop and commercialize certain antimicrobial bacteriophage-derived endolysins for any use other than uses involving topical administration. iNtRON also granted LSG an exclusive option during a specified exclusivity period extending until the expiration of a certain evaluation period to obtain an exclusive license to develop, manufacture and commercialize products containing certain other endolysins. LSG granted iNtRON a non-exclusive, worldwide, sublicensable, royalty-free, license under certain patents and know-how to develop

and commercialize products containing the endolysins licensed under the iNtRON License Agreement formulated for topical administration.

LSG paid iNtRON an upfront fee of $10.0 million and is obligated to pay an option exercise fee to iNtRON upon each exercise of its option to obtain a license to additional endolysins. LSG may also be obligated up pay up to a maximum of $42.5 million in development and regulatory milestone payments (with respect to the originally licensed endolysin), up to a maximum of $37.5 million in development and regulatory milestone payments (with respect to each of any new endolysins) and a maximum of $940.0 million in commercial milestone payments. LSG may also be obligated to pay a tiered low-to-mid teens percentage royalty, subject to certain customary reductions, on net sales of products covered by licensed patents. LSG's royalty obligations apply on product-by-product, country-by-country basis and end upon the latest of (i) the date on which the last valid claim of the licensed patents that covers such licensed product in such country expires, (ii) ten years after the first commercial sale of such licensed product in such country and (iii) the date on which the regulatory exclusivity for such licensed product in such country expires. Unless earlier terminated based on customary termination rights, the iNtRON License Agreement will continue in effect on a product-by-product basis until the expiration of all royalty obligations.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for current and future products and product candidates, technologies and know-how; to operate without infringing, misappropriating or otherwise violating the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We may also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

The patent positions of companies like us are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the fields of genetic therapy, cell therapy, biologics or pharmaceutical products generally has emerged in the United States or in Europe, among other countries. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. We cannot be sure that any patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates and technology. Moreover, our issued patents and those that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our product candidates or technology. The area of patents and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, which may prevent us from commercializing our current and future products and product candidates and practicing our proprietary technology.

Our issued patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related products or technologies or limit the length of the term of patent protection that we may have for our current and future products and product candidates and technologies. In addition, the rights granted under any issued patents may not provide us with complete protection or competitive advantages against competitors or other third parties with similar technology. Furthermore, our competitors may independently develop similar technologies that achieve similar outcomes but

with different approaches. For these reasons, we may have competition for our product candidates. Moreover, the time required for development, testing and regulatory review of our product candidates may shorten the length of effective patent protection following commercialization. For this and other risks related to our proprietary technology, inventions, improvements, platforms and product candidates, please see the section entitled "Risk Factors—Risks Related to Roivant's Business and Industry—Risks Related to Our Intellectual Property."

Patents and Patent Applications

ARU-1801

As of December 1, 2021, ASG has licensed rights to six patent families containing at least 19 issued patents and 20 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims relating to a mutant human-Globin gene, lentiviral vectors and methods for producing lentiviral vectors. These patents and pending applications, if issued, are expected to expire as early as 2035, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Tapinarof

As of December 1, 2021, DSG is the exclusive owner of patent families that include five issued U.S. patents and at least 10 pending U.S. patent applications, as well as more than 25 issued patents and at least 55 pending patent applications in other jurisdictions, including the European Union and Japan, relating to tapinarof, the synthesis of tapinarof, intermediates made in the synthesis, the drug substance crystal form, topical formulations of tapinarof and uses thereof in certain diseases and disorders.

One of these patent families is directed to the topical formulation of tapinarof, and its use to treat plaque psoriasis, that Dermavant has evaluated in Phase 3 clinical trials, as well as its use to treat atopic dermatitis which has been evaluated in Phase 2b clinical trials, which includes a patent that was issued in the United States and has a natural expiration date in 2036, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. This formulation patent includes 113 claims directed to topical, homogeneous, oil-in-water micro-emulsions containing tapinarof, an oil phase, a surfactant and other specific ingredients. DSG also owns an issued patent in the United States covering methods of using the patented formulations to treat inflammatory diseases, including psoriasis and atopic dermatitis. Like the formulation patent, the method-of-use patent has a natural expiration date in 2036 in the United States, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The foreign counterpart formulation and method-of-use applications are pending, and if patents issue from these applications, they will also have a natural expiration date in 2036, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

DSG also owns a drug substance ("DS") patent in the United States covering the high purity crystal form of tapinarof, as DS, the DS synthesis and several novel intermediates that are formed in the synthesis. This DS patent has a natural expiration date in 2038, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. DSG has also filed foreign counterpart DS applications that are still pending in foreign jurisdictions and, if patents issue from these applications, they will similarly have a natural expiration date in 2038, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Genevant

As of December 1, 2021, we own or co-own 16 patent families containing at least 45 issued patents and at least 48 pending patent applications in the U.S., European Union and numerous other jurisdictions, including

claims relating to lipid nanoparticle delivery technology and polymers. These patents and pending applications, if issued, are expected to expire between 2024 and 2041, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 1, 2021, we have licensed 37 patent families containing at least 466 issued patents and at least 217 pending patent applications in the U.S., European Union and numerous other jurisdictions, including claims relating to delivery systems. These patents and pending applications, if issued, are expected to expire between 2021 and 2039, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT-1401

Following ISG's assumption of all rights, title, interest and obligations under the HanAll Agreement from RSG in December 2018, by virtue of the license of patent rights under the HanAll Agreement, ISG is the exclusive licensee of technology directed to IMVT-1401, and certain back-up and next-generation antibodies, and products containing such antibodies, in the licensed territory. As of December 1, 2021, the patent portfolio includes pending patent applications and/or issued patent(s) in the United States and numerous foreign jurisdictions. The in-licensed patent portfolio includes a patent family that discloses anti-FcRn antibodies, pharmaceutical compositions thereof, methods of treating autoimmune disease using the same, polynucleotides encoding such antibodies, expression vectors including such polynucleotides, host cells transfected with such recombinant expression vectors, methods of manufacturing such antibodies and methods of detecting FcRn in vivo or in vitro using such antibodies. This patent family includes an issued U.S. patent with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof as well as a second issued U.S. patent & an allowed U.S. patent application with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, a pharmaceutical composition thereof as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment, polynucleotides and expression vectors encoding the same, host cells capable of expressing the same and methods of producing such antibody or antigen-binding fragment. The patents and pending applications of this patent family, if issued, are expected to expire as early as 2035, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. For information regarding ISG's license agreement with HanAll, please see "—Asset Acquisitions and License Arrangements."

Additionally, as of December 1, 2021, independent of the licensed patent portfolio, ISG has a patent family directed to methods of treating thyroid eye disease using anti-FcRn antibodies that includes patent applications in the United States as well as foreign counterparts in certain jurisdictions within its licensed territory and another patent family that includes an internationally filed patent application directed to methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies. Any patent issued from these patent families is expected to expire in 2039 and 2040, respectively, exclusive of any patent term adjustment or extension.

LSVT-1701

As of December 1, 2021, we have licensed rights to six patent families containing at least 48 issued patents and at least 33 pending patent applications in numerous jurisdictions, including the U.S. and European Union, with claims relating to LSVT-1701, formulations thereof and methods of treatment. These patents and pending applications, if issued, are expected to expire as early as 2027, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Targeted Protein Degradation Platform (Proteovant)

As of December 1, 2021, we have licensed rights to 22 patent families containing three issued U.S. patents, two issued European patents, 25 patents in a number of other jurisdictions and containing at least 71 pending

patent applications in the U.S., Europe and a number of other jurisdictions. These patents and pending applications, if issued, are expected to expire as early as 2037, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We cannot predict whether the patent applications we pursue or license will issue as patents in any particular jurisdiction. Even if our pending patent applications are granted as issued patents, those patents, as well as any patents we license from third parties now or in the future, may be challenged, circumvented or invalidated by third parties. While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or technologies may provide sufficient basis for a competitor or other third party to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates. Consequently, we may not obtain or maintain adequate patent protection for any of our products or product candidates.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. A U.S. patent also may be accorded patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for PTEs on patents covering products eligible for PTE. We plan to seek PTEs for any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. The actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our products or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see “Risk Factors—Risks Related to Roivant’s Business and Industry—Risks Related to Our Intellectual Property.”

Trade Secrets

In addition to our reliance on patent protection for our inventions, product candidates and research programs, we also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. As a result, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Roivant's Business and Industry—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, including gene therapies, as well as diagnostics, and any future product candidates. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized, or cleared by the applicable regulatory authority.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations and biologics under the FDCA and the Public Health Service Act (the "PHSA"), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, debarment from producing or marketing drug products or biologics, disqualification from conducting research, and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Our product candidates must be approved by the FDA through either an NDA or a BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB, or independent ethics committee at each clinical trial site before each human trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and requirements, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA inspection of the clinical trial sites that generated the data in support of the NDA or BLA and/or us as the sponsor
- payment of user fees for FDA review of the NDA or BLA (unless a fee waiver applies)
- agreement with FDA on the final labeling for the product and the design and implementation of any required REMS; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any drug, biological or gene therapy candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. In the U.S., the conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

In the U.S., an IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue, and additional preclinical testing may commence, after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Additionally, the review of information in an IND submission may prompt FDA to, among other things, scrutinize existing INDs or marketed products and could generate requests for information or clinical holds on other product candidates or programs.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all

research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. In the U.S., each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules had historically been subject to review by the NIH Recombinant DNA Advisory Committee (the "RAC"), of the NIH Office of Biotechnology Activities (the "OBA"), pursuant to the NIH Guideline. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closed October 16, 2018, the NIH announced that it will no longer accept new human gene transfer protocols for review as a part of the protocol registration process or convene the RAC to review individual clinical protocols. In April 2019, NIH announced the updated guidelines, which reflect these proposed changes, and clarify that these trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its

safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

In August 2018, the FDA released a draft guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development, i.e., the first-in-human clinical trial, to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA or post-approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected AEs, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from

company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act (the "PDUFA"), as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification. During the COVID-19 pandemic, because of travel and other restrictions, the FDA has significantly curtailed its inspection program. The reduction in pre-approval inspections has resulted in delays to some product approvals. There may be delays to product approvals in the future based on continuing problems with respect to the FDA's ability to conduct inspections and then, even after a resumption of the FDA's normal inspection program, a possible backlog in applications under review by the agency.

The FDA has developed the Oncology Center of Excellence RTOR pilot program to facilitate a more efficient review process for certain oncology product candidates. Although this program allows FDA to begin reviewing clinical data prior to submission of a complete NDA or BLA, the program is not intended to change the PDUFA review timelines.

Before approving an NDA or BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require the applicant to obtain additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and/or to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or

request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher (a "PRV"). A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program through September 30, 2024, with the potential for PRVs to be granted through September 30, 2026.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the development, FDA review and approval of new drugs and biologics that meet certain criteria. For

example, the FDA has a fast-track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

A product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review and accelerated approval. Priority review means that, for a new molecular entity or original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A product is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review. If criteria are not met for priority review, the application for a new molecular entity or original BLA is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition, generally provides a meaningful advantage over other available therapies, and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast-track designation, which means that the sponsor may file sections of the NDA or BLA for review on a rolling basis if certain

conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

As part of the 21st Century Cures Act, Congress amended the FDCA to facilitate an efficient development program for, and expedite review of regenerative medicine advanced therapies ("RMATs"), which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. RMATs do not include those human cells, tissues, and cellular and tissue-based products regulated solely under section 361 of the PHSA and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A drug sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND although ideally no later than the end-of-Phase 2 meeting. The FDA has 60 calendar days to determine whether the therapy meets the criteria, including whether there is preliminary clinical evidence indicating that the product has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

The FDA has also announced the availability of the RTOR pilot program for oncology product candidates that are likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications and candidates meeting other criteria for other expedited programs, such as fast track and priority review. Submissions for RTOR consideration should also have straightforward study designs and endpoints that can be easily interpreted (such as overall survival or progression free survival). Acceptance into the RTOR pilot does not guarantee or influence approvability of the application, which is subject to the usual benefit-risk evaluation by FDA reviewers, but the program allows FDA to review data earlier, before an applicant formally submits a complete application. The RTOR pilot program does not affect FDA's PDUFA timelines.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval, breakthrough therapy and RMAT designation do not change the standards for approval.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (the "PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act (the "FDASIA"), amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives

and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences and certain problems in the manufacturing process, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and any promotion that is false or misleading, and a company that is found to have improperly promoted off-label uses or in a false or misleading manner may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals;
- drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties; or
- debarment from producing or marketing drug products or biologics.

Regulation of Companion Diagnostics

Success of certain product candidates may depend, in part, on the development and commercialization of a companion diagnostic. A companion diagnostic is a medical device, often an *in vitro* device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. Companion diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are generally regulated as medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance through the premarket notification process ("510(k) clearance") or premarket approval from the FDA prior to commercialization.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a premarket approval application ("PMA"). In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the

safety and effectiveness of the device. For diagnostic tests, a PMA, typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will typically conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation (the "QSR"), which requires manufacturers to follow design, testing, control, corrective and preventative action, documentation, and other quality assurance procedures. The FDA's review of an initial PMA application is generally required by statute to take six months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of FDA's quality system regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug and biologic makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA is able to conduct an inspection of the product(s) and the company's facilities for compliance with its authorities.

FDA has taken the position that developers of companion diagnostic tests associated with novel therapeutic products should seek clearance or approval at the same time that the therapeutic developer seeks approval. FDA has recognized that contemporaneous clearance or approval of a companion diagnostic with a therapeutic is not always possible, though FDA has indicated that coordination of contemporaneous clearances/approvals is a policy goal. In October 2018, FDA issued a safety alert warning against the use of unapproved or uncleared genetic tests to predict patient response to specific medications. While FDA has historically exercised enforcement discretion against laboratory developed tests—tests which are developed and performed in a single Clinical Laboratory Improvement Amendments (CLIA) certified laboratory—the 2018 alert and a subsequent 2019 Warning Letter against Inova Genomics Laboratory suggest that FDA may prioritize for enforcement certain uncleared or unapproved tests marketed as companion diagnostic tests. Subsequently, FDA has attempted to encourage collaboration between *in vitro* diagnostic test developers and therapeutic developers and to clarify FDA expectations as to companion diagnostic labeling, particularly through guidance in the oncology area. In June 2021, the Verifying Accurate Leading-edge IVCT Development Act of 2021 (the "VALID Act") was introduced in the U.S. House of Representatives and Senate. Similar to the 2020 iteration of the bill, among other things, the VALID Act would likely classify all companion diagnostic tests as requiring FDA premarket review and would formalize and arguably expand FDA's regulatory authority over diagnostic testing. Though passage of the VALID Act is uncertain, strong bipartisan support remains for some kind of diagnostic testing legislative reform in the near term.

Biosimilars and Exclusivity

Certain of our product candidates, including IMVT-1401 and ARU-1801, are regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (the "BPCI Act"), as part of the Affordable Care Act (the "ACA"). This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be

alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare and Medicaid Services (the "CMS"), the Office of Inspector General and Office for Civil Rights, other divisions of the Department of HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and physicians and any future arrangements with third party payers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and HIPAA.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing certain billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to federal, state, and commercial reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under this law.

HIPAA created federal criminal statutes that prohibit among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

We are subject to data privacy and security regulations administered and enforced by the federal government as well as statutes and regulations adopted in the states in which we conduct our business. At the federal level, the data privacy and security regulations implementing HIPAA, as amended by the Health Information and Technology for Economic and Clinical Health Act, mandate, among other things, compliance with standards relating to the privacy and security of individually identifiable health information, which requires, among other things, the adoption of administrative, physical and technical safeguards to protect such information. Civil and criminal penalties may be imposed on entities subject to HIPAA, both by the HHS Office for Civil Rights and by state attorneys general, who have the authority to file civil actions for damages or injunctions in federal courts to enforce the HIPAA privacy and security regulations and to seek attorney's fees and costs associated with pursuing such actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties. Further, the states are rapidly expanding their data privacy and security laws and we may be subject to a variety of different restrictions and requirements under such laws.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act"), within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians, certain other healthcare professionals, and teaching hospitals and to report

annually certain ownership and investment interests held by physicians, certain other healthcare professionals, and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not preempted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the changes made by the ACA to preexisting law of importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price ("AMP"), and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.
- imposed a requirement on manufacturers of branded drugs to provide a 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.
- expanded the entities eligible for discounts under the 340B Drug Discount Program.
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Most recently, the Supreme Court upheld the constitutionality of the law in June 2021; however, future legal disputes remain possible. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA, and the law may be subjected to various Executive Orders and/or regulatory action to expand or reduce the scope of the law, based on the administration controlling the White House. The implementation of the ACA is ongoing, and the law may continue to exert significant pressure on pharmaceutical pricing and our profitability.

Moreover, in May 2018, the Trump administration released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint, and former President Trump also issued a number of Executive Orders in 2020 that were aimed at lowering the prices of prescription drugs. Some rules enacted under the Trump Administration have been stayed as a result of pending litigation or are under review or have been rescinded by the Biden Administration. For example, a rule enacted under the Trump Administration known as the "Most Favored Nations" rule would set Medicare Part B reimbursement at an amount no higher than the lowest price that a drug manufacturer receives on a particular product in an index of foreign countries. This rule currently was the subject of litigation, and was formally rescinded the Biden Administration in August 2021. Other initiatives under the Trump administration have taken effect. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a form of drug utilization management, for Part B drugs beginning January 1, 2020.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013, following passage of the Bipartisan Budget Act of 2013, and will remain in effect through 2029 unless additional congressional action is taken. Pursuant to the CARES Act and subsequent legislation, these reductions were suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. As the legislation currently stands, the reductions will go back into effect as of January 2022 and remain in effect through 2030 unless additional Congressional action is take, The American Rescue Plan Act of 2021 eliminates the Medicaid unit rebate cap effective as of January 1, 2024, and the removal of this rebate cap could significantly impact our Medicaid rebate liability beginning in 2024.

Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, require drug pricing negotiations in Medicare, redesign the Part D benefit to lower patient costs and overall spending, introduce enhanced transparency measures into drug pricing, and reform government program reimbursement methodologies for drugs, for example, by introducing inflationary penalties for Parts B and D drugs. The Biden Administration has indicated that lowering prescription drug prices is a priority. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Additionally, Democratic leadership has elected to pursue drug pricing reform as a part of a broader legislative package encompassing President Biden's Build Back Better reconciliation bill, which aims to incorporate components of H.R. 3 passed by the House of Representatives in 2020. In particular, H.R. 3 would require the federal government to negotiate the pricing for certain prescription drugs and set a cap on the price Medicare would pay that is tied to the price of the drug in other wealthy nations. Manufacturers also would face fines if their drug prices increase faster than the rate of inflation. The Build Back Better Act, as well as various other legislative proposals, also include reforms to redesign the Part D benefit to protect beneficiaries from high out-of-pocket costs and reduce overall program spending. We cannot predict whether these or other drug pricing initiatives will be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or

restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the

FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

European Union and United Kingdom Drug Development

In the European Union and European Economic Area and United Kingdom, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union and European Economic Area and United Kingdom are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC (the “Directive”), has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently into their national laws, including in the UK. This has led to significant variations in the Member State regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU/UK countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (the “NCA”), and one or more Ethics Committees (“ECs”). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the country where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014 (the “Regulation”), which is set to replace the current Directive. Specifically, the new Regulation, which will be directly applicable in all Member States without the need for EU Member States to transpose it into national law, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. Following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the Regulation, through an independent audit, the System will go live at the end of Janurary 2022. This Regulation will not be applicable in the UK.

European Union and United Kingdom Drug Marketing

Much like the federal Anti-Kickback Statue prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union and European Economic Area and United Kingdom. The provision of benefits or advantages to induce or reward improper performance generally is governed by Directive 2001/83/EC as implemented in the relevant country, the national anti-bribery

laws of the European Union Member States, and the Bribery Act 2010 in the UK, as well as the industry Codes of Practice that are based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the national laws of the EU Member States, as well as in the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Depending on the applicable national rules in the EU Member States and the UK, payments and other transfers of value made to physicians, physician associations, medical students, healthcare organizations, patient organizations and other stakeholders in the EU Member States, the UK and Member States of the European Economic Area must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual country. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the relevant country. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Union and United Kingdom Drug Review and Approval

In the European Economic Area (the "EEA"), which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). There are two types of marketing authorizations which, however, are based on identical regulatory rules, requirements and timelines, including identical requirements concerning the presentation and content of the application for marketing authorization.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (the "CHMP"), of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

  Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application (a "MAA"), by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope

of the centralized procedure. If a product is to be authorized in more than one Member State, the assessment procedure is coordinated between the relevant EU Member States. Where a product has already been authorized for marketing in a Member State of the EEA, the national MA can be recognized in another Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (the "RMS"). The competent authority of the RMS coordinates the preparation of a draft assessment report, a draft summary of the product characteristics (the "SmPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States) for their final approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging circulated by the RMS, the coordinated procedures is closed, and the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above-described procedures, during the assessment of the documents submitted in the MAA and before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized MAs (under the Northern Irish Protocol of the Withdrawal Agreement, centralized MAs will continue to apply in Northern Ireland). All medicinal products with a valid centralized MA as of December 31, 2020, were automatically converted to Great Britain MAs on January, 1 2021 (unless the MA holder opted out of this procedure). For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. The MHRA also has the power to have regard to MAs approved in EEA Member States through decentralized or mutual recognition procedures with a view to more quickly granting a MA in the United Kingdom or Great Britain.

European Union and United Kingdom New Chemical Entity Exclusivity

In the EEA and UK, innovative medicinal products, approved on the basis of a full dossier of preclinical and clinical data as part of the MAA, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference innovative product when applying for a generic or biosimilar MA in the EEA/UK, for a period of eight years from the date of authorization of the reference product. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, however, another company may market another version of the product if such company obtained a MA based on a marketing authorization application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials (i.e. without cross-referencing to the data within the reference innovative product).

European Union and United Kingdom Orphan Designation and Exclusivity

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions and either (i) such condition affects not more than five in 10,000 persons in the EEA, or (ii) it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development. In either case, the applicant must also demonstrate that no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected compared to the product available).

In the EEA, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers. In addition, if the criteria for orphan designation are found to be maintained at the time of authorization of the product, ten years of market exclusivity is granted following grant of an orphan marketing authorization. During this market exclusivity period, neither the EMA nor the European Commission nor any of the competent authorities in the EEA Members States can accept an application or grant a marketing authorization for a "similar medicinal product" for the same indication. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This orphan exclusivity period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity may also be broken, so a similar product may be authorized for the same indication, in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to the authorized product; (ii) the marketing authorization holder consents to the grant of the similar product; or (iii) the marketing authorization holder cannot supply enough orphan medicinal product. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The upcoming legislative reforms in the EU, which are part of the new EU Pharmaceutical Strategy and some of which could materialize as early as 2022, may result in a reduction of market exclusivity periods for orphan medicinal products and/or imposition of additional requirements for grant of such exclusivity.

From January 1, 2021, a separate process for orphan drug designation has applied in Great Britain. There is no pre-marketing authorization orphan designation (as there is in the EEA) and the application for orphan designation will be reviewed by the MHRA at the time of the marketing authorization application. The criteria are the same as in the EEA, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain). Orphan exclusivity granted to a centralized marketing authorization will also apply in Northern Ireland.

European Union and United Kingdom Pediatric Investigation Plan

In the EEA and UK, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (a "PIP"), agreed with the EMA's Pediatric Committee (a "PDCO") or MHRA as relevant. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO/MHRA can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO/MHRA when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. If a marketing authorization is obtained and trial results are included in the product information, even when negative, and the product is approved in all Member States, non-orphan products are eligible for six months' supplementary protection

certificate extension. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

The upcoming legislative reforms in the EU, which are part of the new EU Pharmaceutical Strategy and some of which could materialize as early as 2022, may result in a reduction of the above pediatric rewards and/or imposition of additional requirements for grant of rewards.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable in the United Kingdom. However this ended on December 31, 2020. On December 30, 2020, the United Kingdom and European Union signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties. Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorizations, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the United Kingdom in the long term. The MHRA has published detailed guidance for industry and organizations to follow now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products and medical devices evolves over time. There are also a number of ongoing consultations on the future legislation in the UK.

European Union and United Kingdom data protection regime

The processing of personal data, including health data, in the EEA is governed by the General Data Protection Regulation (the "GDPR"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the European Union or EEA or the monitoring of the behavior of data subjects in the European Union or EEA. The GDPR enhances data protection obligations for data controllers of personal data, including *inter alia* stringent requirements relating to lawful and legitimate basis and purposes for the processing of personal data, the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, appointment of a data protection officers, conclusion of data processing agreements, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Until recently, one such data transfer mechanism was the EU-US Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the CJEU. The CJEU upheld the validity of standard contractual clauses ("SCCs") as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA and the U.K., need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. It remains to be seen whether SCCs will remain available and whether additional means for lawful data transfers will become available. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR.

In addition, further to the United Kingdom's exit from the European Union on January 31, 2020, the GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the United Kingdom's data protection regime, which is independent from but aligned to the European Union's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. With respect to transfers of personal data from the EEA to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

Rest of the World Regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and

Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act (the "FCPA"), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Further, other anti-corruption laws, such as the UK Bribery Act, are broader and can regulate payments to non-governmental entities.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are covered or paid for by the federal or national government as well as commercial managed care organizations, pharmacy benefit managers, and similar healthcare management organizations.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the acquisition costs and reimbursement for drug products may lower than within the United States.

In the United States, the decisions about reimbursement for new drug products under the Medicare program are made by CMS, an agency within HHS. CMS determines coverage standards for products reimbursed by Medicare, and private payors often adopt coverage standards established by CMS for the commercial marketplace. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor.

Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Further, due to the COVID-19 pandemic, millions of individuals have lost or are expected to lose employer-based insurance coverage, which may adversely affect our ability to successfully commercialize our products.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs

of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs, a manufacturer must enter into agreements with the Secretary of HHS to participate in the Medicaid Drug Rebate Program and the 340B drug discount program. Under the Medicaid Drug Rebate Program, manufacturers are obligated to pay rebates to the State Medicaid Programs on each unit of the manufacturer's drugs that are reimbursed by State Medicaid Programs—both with regard to Medicaid Fee for Service and Medicaid Managed Care. Additionally, under the 340B drug discount program, manufacturers extend discounts to "covered entities" eligible to participate in the 340B program, including various hospital providers. The required 340B discount on a given product is calculated based on the average manufacturer price (the "AMP") and Medicaid rebate amounts reported and paid by the manufacturer under the Medicaid Drug Rebate Program. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under current law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on drugs that receive an orphan designation by the FDA. As 340B drug pricing is determined based on AMP and Medicaid rebate data, revisions to the statute and regulations governing the Medicaid Drug Rebate Program may cause the required 340B discount to increase. Additional legislation surrounding the 340B program, including which providers are eligible for the program, may be enacted in the future. These developments could affect our profitability.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union and UK, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes or the amount of profit made on those profits, and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Human Capital Management

As of September 30, 2021, we and our subsidiaries had approximately 650 full-time employees.

Our human capital objectives include sourcing, recruiting, retaining, incentivizing and developing our existing and future employees. We seek to create nimble, entrepreneurial Vants that operate similar to independent biotechnology companies where each management team, comprised of world-class drug developers and clinical operators, is solely focused on their respective Vant's mission. Our and our Vants' equity incentive plans are designed to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards to encourage focus and calculated risk-taking. In connection with becoming a public company, we expect to hire additional personnel and to implement procedures and processes to address public company regulatory requirements and customary practices.

Corporate and Other Information

We were registered as an exempted limited company in Bermuda in 2014, under the name Valor Biotechnology Ltd. In November 2014 we changed our name to Roivant Sciences Ltd. Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, United Kingdom. Our telephone number is +44 207 400 3347.

Our web page address is https://roivant.com. Our investor relations website is located at https://investor.roivant.com/. We will make available free of charge on our investor relations website under "SEC Filings" our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors' and officers' Section 16 Reports and any amendments to those reports after filing or furnishing such materials to the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC.

We are an "emerging growth company" (an "EGC"), as defined in the Jumpstart Our Business Startups Act of 2012. As an EGC, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation.

Legal Proceedings

We are involved in various claims and legal actions arising in the ordinary course of business. In the opinion of management, the ultimate disposition of these matters will not have a material adverse effect on our consolidated financial position, results of operations or liquidity.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information, as of December 1, 2021, regarding Roivant's executive officers and directors. The executive officers of Roivant are employees of Roivant Sciences, Inc., a wholly owned subsidiary of Roivant, and provide services pursuant to an inter-company agreement. For biographical information concerning the executive officers and directors, see below.

Name	Age	Position
Executive Officers		
Matthew Gline	37	Chief Executive Officer and Director
Eric Venker	35	President and Chief Operating Officer
Mayukh Sukhatme	46	President and Chief Investment Officer
Richard Pulik	42	Chief Financial Officer
Rakhi Kumar	41	Chief Accounting Officer
Directors		
Vivek Ramaswamy	36	Founder and Chair
Andrew Lo	61	Director
Patrick Machado	57	Director
Keith Manchester	53	Director
Ilan Oren	37	Director
Daniel Gold	53	Director
Masayo Tada	76	Director
James C. Momtazee	49	Director

Executive Officers

Matthew Gline has served as our Chief Executive Officer since January 2021 and as a Director of Roivant from the closing of the Business Combination in September 2021. Mr. Gline joined Roivant in March 2016 and previously served as Chief Financial Officer, from September 2017 through his appointment as Chief Executive Officer, and as Senior VP, Finance and Business Operations. Prior to joining Roivant, Mr. Gline was a Vice President at Goldman Sachs, Fixed Income Digital Structuring, from 2014 to 2016, and co-founded Fourthree, a risk analytics technology and consulting company, from 2012 to 2014. Mr. Gline earned his A.B. in Physics from Harvard College. Our board of directors believes that Mr. Gline's experience in various roles at our company and his prior professional experience qualify him to serve as a member of our board of directors.

Eric Venker has served as our President and Chief Operating Officer since January 2021 and, prior to that role, as Chief Operating Officer, from November 2018. From October 2017 to October 2018, Dr. Venker served as Chief of Staff to our Chief Executive Officer, and from 2014 to 2015, as an Analyst at Roivant. From 2015 to 2017, Dr. Venker was a physician at New York Presbyterian Hospital/Columbia University Medical Center, where he trained in internal medicine, and also served as Chair of the Housestaff Quality Council leading operational initiatives to improve efficiencies. From 2011 to 2015, Dr. Venker was a Clinical Pharmacist at Yale-New Haven Hospital. Dr. Venker also serves on the boards of directors of Immunovant, Arbutus Biopharma, Sio Gene Therapies and several private biopharmaceutical companies. He received his Pharm.D. from St. Louis College of Pharmacy and his M.D. from Yale School of Medicine.

Mayukh Sukhatme has served as our President and Chief Investment Officer since January 2021, overseeing the creation and support of biopharmaceutical companies in the Roivant family. Dr. Sukhatme joined Roivant in 2015 and previously served as President of Roivant Pharma and as our Chief Business Officer. From 2000 to 2015, Dr. Sukhatme was a healthcare-focused analyst and portfolio manager for several large institutional investment firms, including both public markets and venture capital firms. His principal focus was

on development-stage biotechnology and pharmaceutical companies, where he led diligence and investment decisions on numerous companies and pharmaceutical compounds across a wide variety of therapeutic areas. Dr. Sukhatme earned his M.D. from Harvard Medical School and his B.S. in Biology and B.S. in Literature from MIT.

Richard Pulik has served as our Chief Financial Officer since October 2021. Prior to joining Roivant, Mr. Pulik was the Global Head of Business Development & Licensing and Portfolio Management, Oncology at Novartis and a member of Novartis's Innovation Management Board and the Novartis Oncology Leadership Team, from August 2019 to September 2021. Mr. Pulik joined Novartis in 2012 as a Senior Director, Mergers & Acquisitions based in Basel, Switzerland working on the strategy and execution of the deals that shaped Novartis. In 2015, Mr. Pulik was appointed as Vice President, Head of North America Investor Relations for Novartis. Prior to these roles at Novartis, Mr. Pulik worked at Bank of America Merrill Lynch, Monitor Group and UBS Investment Bank, focusing on mergers and acquisitions and strategy in the healthcare sector. Mr. Pulik received a B.S. in Finance from The Wharton School and a B.A. in Economics and International Relations at the University of Pennsylvania in 2001.

Rakhi Kumar has served as our Chief Accounting Officer since August 2018, leading the accounting and financial operations and related internal controls functions. Ms. Kumar joined Roivant in September 2015, and previously served as Vice President, Finance and External Reporting. Prior to joining Roivant, Ms. Kumar was responsible for external reporting, corporate and technical accounting at The Medicines Company from 2013 to 2015. Earlier in her career, Ms. Kumar was in the assurance services at Ernst and Young. Ms. Kumar also serves as a director and as chair of the audit committee for NeuroPace (Nasdaq: NPCE), a medical device company. She is a licensed Certified Public Accountant and a Chartered Professional Accountant in Ontario, Canada. She received her M.S. in Accounting and Taxation from the University of Hartford.

Directors

Vivek Ramaswamy is our Founder and Chair of our board of directors. He has also served as our Executive Chairman since January 2021 and, prior to taking that role, as Chief Executive Officer, from May 2014. Mr. Ramaswamy previously served as a member of the investment team at QVT Financial, from 2007 to 2014. Mr. Ramaswamy was previously as a director of Myovant Sciences, Axovant Sciences and Arbutus Biopharma. Mr. Ramaswamy received his A.B. in Biology from Harvard College and his J.D. from Yale Law School, where he was a Paul & Daisy Soros Fellow. Our board of directors believes that Mr. Ramaswamy's status as our Founder and his extensive prior experience in the biopharmaceutical industry qualifies him to serve as a member of our board of directors.

Andrew Lo has served as a Director of Roivant since 2016. He is a Charles E. and Susan T. Harris Professor at MIT Sloan School of Management since 1988, Founder and Chairman of QLS Advisors since 2019, Member of Thalēs Advisory Board since 2019, Chairman Emeritus and Senior Advisor of AlphaSimplex Group since 2018 and member of the Competitive Market Advisory Counsel of the Chicago Mercantile Exchange since 2013. Dr. Lo has served as Director of BridgeBio Pharma since 2020 and advisor of the same company from 2015 to 2020. Our board of directors believes that Dr. Lo's extensive experience as director and advisor of various companies, including in the biopharmaceutical industry, qualifies him to serve as a member of our board of directors.

Patrick Machado has served as a Director of Roivant since 2017. He was a co-founder of Medivation, Inc., a biopharmaceutical company, and served on its board of directors from April 2014 through its acquisition by Pfizer in 2016. Mr. Machado also served as Medivation's Chief Financial Officer from its inception in September 2003 and as its Chief Business Officer from December 2009, in each case through 2014. Since 2014, Mr. Machado has served as a professional independent board member to more than 15 private and public biotechnology companies, including Medivation (acquired by Pfizer), Endocyte (acquired by Novartis), Principia (acquired by Sanofi) and Therachon (acquired by Pfizer). Mr. Machado received a J.D. from Harvard Law

School and a B.A. and B.S. in German and Economics, respectively, from Santa Clara University. Our board of directors believes that Mr. Machado's extensive experience as director and officer in the biopharmaceutical industry qualifies him to serve as a member of our board of directors.

Keith Manchester has served as a Director of Roivant since 2014. He serves as a Partner and the Head of Life Sciences at QVT Financial, New York, USA, an investment firm, where he has been employed since 2005. He focuses on investments in both publicly traded and privately owned life science companies. Prior to joining QVT, Dr. Manchester was Vice President of Business Development from 2002 to 2004 and Director of Business Development from 2000 to 2002 at Applied Molecular Evolution, a biotechnology company. From 1999 to 2000, Dr. Manchester was an associate at Vestar Capital Partners, a private equity firm. From 1997 to 1999, Dr. Manchester was an investment banker in the healthcare group at Goldman, Sachs & Co. He received his A.B. from Harvard College and his M.D. from Harvard Medical School. Dr. Manchester serves as a director for the following companies: Roivant Sciences Ltd., Roivant Sciences, Inc., Arbutus Biopharma Corporation, and Kriya Therapeutics. Dr. Manchester also sits on the Supervisory Board of Medigene AG. Our board of directors believes that Dr. Manchester's extensive experience investing in the life sciences industry qualifies him to serve as a member of our board of directors.

Ilan Oren has served as a Director of Roivant since 2014. He has served as Co-Chief Executive Officer of Dexcel Pharma, a privately-owned Israeli group of pharmaceutical companies, since November 2019. Prior to serving as Co-CEO, Ilan served as Vice President for the group and led corporate and business development activities, including formation of strategic ventures, product partnerships, product portfolio selection, product acquisitions, strategic investments, and mergers and acquisitions. He holds an A.B. in Economics from Harvard College. Our board of directors believes that Mr. Oren's extensive experience as a high-level executive in the pharmaceutical industry qualifies him to serve as a member of our board of directors.

Daniel Gold has served as a Director of Roivant since 2020. Mr. Gold serves as the CEO, managing partner and founder of QVT Financial LP, an asset management company with offices in New York and New Delhi. QVT Financial, through its managed and affiliated multi-strategy funds, is an experienced global investor in multiple industries, including biotech, financial, shipping and offshore industries. Mr. Gold founded QVT Financial LP in 2003. Mr. Gold holds an A.B. in Physics from Harvard College. Mr. Gold also currently serves on the board of public companies MP Materials, Okeanis Eco Tankers Corp. and Awilco Drilling PLC, in addition to various private companies. Our board of directors believes that Mr. Gold's extensive experience investing in the life sciences industry qualifies him to serve as a member of our board of directors.

Masayo Tada has served as a Director of Roivant since 2019. He has served as Chairman of the Board of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") since April 2018 and as a Director since April 2021, having previously served as Representative Director from April 2008 to March 2021. Prior to serving as Chairman of Sumitomo, he served as President and CEO of Sumitomo since June 2008, as well as other positions since 2005. Our board of directors believes that Mr. Tada's extensive experience as a director and high-level executive in the pharmaceutical industry qualifies him to serve as a member of our board of directors.

James C. Momtazee has served as a Director of Roivant from the closing of the Business Combination in September 2021. Mr. Momtazee is the Managing Partner of Patient Square Capital, a dedicated health care investing firm. Mr. Momtazee has over 25 years of investment and acquisition experience, the vast majority of which was focused on the health care sector. Prior to founding Patient Square, he held various positions at KKR & Co., Inc. ("KKR") since 1996. He helped form KKR's health care industry group in 2001 and ran that team for over 10 years. Mr. Momtazee currently also serves on the board of directors of BridgeBio Pharma, Apollo Therapeutics, Kriya Therapeutics and the Medical Device Manufacturers Association and has previously served on the board of directors of multiple other health care companies, including PRA Health Sciences, Inc. (lead independent director), Envision Healthcare, Heartland Dental, Ajax Health, Global Medical Response, BrightSpring Health Services, Covenant Surgical Partners, Entellus Medical, Inc., EchoNous, Spirox, Inc., Arbor

Pharmaceuticals, Lake Region Medical, HCA Healthcare, Jazz Pharmaceuticals, and Alliance Imaging. Our board of directors believes that Mr. Momtazee's extensive experience investing in the biopharmaceutical industry qualifies him to serve as a member of our board of directors.

Family Relationships

There are no family relationships between the members of our board of directors and our executive officers.

Board of Directors

Our business and affairs are managed under the direction of our board of directors. Our board of directors consists of nine members, with Vivek Ramaswamy serving as Chair. Our amended and restated bye-laws provide for a classified board of directors divided into three classes serving staggered three-year terms as follows:

- Class I directors are Mr. Machado, Dr. Manchester and Mr. Gline, and they will serve until our annual meeting of shareholders in 2022;
- Class II directors are Mr. Gold, Dr. Lo and Mr. Ramaswamy, and they will serve until our annual meeting of shareholders in 2023; and
- Class III directors are Mr. Tada, Mr. Oren and Mr. Momtazee, and they will serve until our annual meeting of shareholders in 2024;

At each annual meeting of shareholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our board of directors could have the effect of increasing the length of time necessary to change the composition of a majority of the board of directors. Our amended and restated bye-laws provide that the authorized number of directors (being no less than 5 directors and no more than 15 directors) may be changed only by resolution approved by a majority of our board of directors.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and has considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that each of Mr. Machado, Dr. Manchester, Mr. Gold, Dr. Lo, Mr. Oren and Mr. Momtazee, representing six of the nine individuals expected to serve as members of our board of directors, are independent, as that term is defined under the applicable rules and regulations of the SEC and the Nasdaq listing rules. We comply with the corporate governance requirements of the SEC and the Nasdaq listing rules.

We comply with the requirements of Rule 10A-3 of the Exchange Act and the Nasdaq listing rules, which rules require that our audit committee be composed of at least three members. Under Rule 10A-3 of the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in Rule 10A-3 of the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing.

Committees of the Board of Directors

Our board of directors established an audit committee, a compensation committee and a nominating and governance committee, each of which has the composition and responsibilities described below. From time to time, our board of directors may establish other committees to facilitate the management of our business.

Audit Committee

The members of our audit committee are Mr. Momtazee (Chair), Mr. Machado and Mr. Oren. The composition of our audit committee meets the requirements for independence under the current Nasdaq listing
standards and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Mr. Momtazee is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation will not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

The members of our compensation committee are Mr. Gold (Chair), Mr. Machado and Mr. Oren. Each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code, and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- reviewing and approving the compensation of our Principal Executive Officer, each of our other executive officers and Mr. Ramaswamy;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our stock and equity incentive plans;
- reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and
- reviewing our overall compensation philosophy.

Nominating and Governance Committee

The members of our nominating and governance committee are Dr. Lo (Chair), Dr. Manchester and Mr. Momtazee. Dr. Lo, Dr. Manchester and Mr. Momtazee meet the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- identifying and recommending candidates for membership on our board of directors;
- developing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of conduct for directors, executive officers and other senior financial officers;

- overseeing the process of evaluating the performance of our board of directors; and
- assisting our board of directors on corporate governance matters.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

Our board of directors has adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that is currently applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.roivant.com. The nominating and governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Director Compensation

See "Executive and Director Compensation" for information regarding compensation paid to our directors.

EXECUTIVE AND DIRECTOR COMPENSATION

Roivant's named executive officers ("NEOs") for Roivant's fiscal year ended March 31, 2021 ("Fiscal 2020"), each of whom was an employee of Roivant Sciences, Inc. ("RSI"), a wholly owned subsidiary of Roivant, during Fiscal 2020 are as follows:

- Matthew Gline, Chief Executive Officer and former Chief Financial Officer;
- Eric Venker, President and Chief Operating Officer;
- Benjamin Zimmer, former President, Roivant Health; and
- Vivek Ramaswamy, Founder, Executive Chairman and former Chief Executive Officer.

Summary Compensation Table

The following table sets forth information regarding the compensation paid to the NEOs in respect of Fiscal 2020.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(3)	Total ($)
Matthew Gline Chief Executive Officer and former Chief Financial Officer(4)	2020	$350,000	$455,000	—	$7,497,000	—	$ 8,550	$ 8,310,550
Eric Venker President and Chief Operating Officer	2020	$275,000	$455,000	$5,734,500	$3,748,500	—	$ 83,550	$10,296,550
Benjamin Zimmer Former President, Roivant Health(5)	2020	$350,000	$455,000	—	$5,247,900	—	—	$ 6,052,900
Vivek Ramaswamy Founder, Executive Chairman and Former Chief Executive Officer(4)	2020	$350,000	—	—	—	—	$ 11,800	$ 361,800

(1) The amounts reported in this column reflect the annual cash discretionary performance bonus paid to each of the NEOs in respect of Fiscal 2020, which were earned and paid based on an assessment by our board of directors of overall company and individual performance for Fiscal 2020.

(2) The amounts reported in this column represent the aggregate grant date fair value of the awards of restricted stock units ("RSUs") and nonqualified stock options granted to each of the NEOs during Fiscal 2020 under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan ("2015 EIP") and as described in further detail below. The grant date fair value was calculated in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The amounts reported for any awards subject to performance conditions were calculated based on the probable outcome of the performance conditions as of the grant date, consistent with the estimate of aggregate compensation cost to be recognized over the service period determined as of the grant date under FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used in calculating such grant date fair value are set forth in the notes to Roivant's audited consolidated financial statements included elsewhere in this prospectus. Amounts reported do not reflect the actual economic value that may be realized by the applicable NEO.

The grant date fair value of the RSUs granted to Dr. Venker in Fiscal 2020, if the maximum level of the applicable performance conditions were achieved, is $5,734,500.

The following are the grant date fair values of the stock options granted to the NEOs in Fiscal 2020, if the maximum level of the applicable performance conditions were achieved: Mr. Gline ($7,497,000), Dr. Venker ($3,748,500) and Mr. Zimmer ($5,247,900).

(3) The amounts reported for Fiscal 2020 in this column reflect the following:

(a) For Mr. Gline, reflects company matching contributions under RSI's 401(k) plan ($8,550);

(b) For Dr. Venker, reflects (i) company matching contributions under RSI's 401(k) plan ($8,550) and (ii) fees received by Dr. Venker in Fiscal 2020 for his service on the board of directors of certain private company affiliates of Roivant ($75,000); and

(c) For Mr. Ramaswamy, reflects company matching contributions under RSI's 401(k) plan ($11,800).

(4) Effective January 26, 2021, Mr. Ramaswamy ceased serving as Roivant's Chief Executive Officer and transitioned to his current role as Executive Chairman. In addition, effective as of such date, Mr. Gline, Roivant's then-current Chief Financial Officer, was appointed to serve as Chief Executive Officer. Effective as of September 28, 2021, Mr. Gline ceased serving as Roivant's Chief Financial Officer upon the appointment of Richard Pulik as Chief Financial Officer.

(5) Mr. Zimmer has transferred from the role of President, Roivant Health to the role of Chief Executive Officer of a newly-formed Vant.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information concerning outstanding equity awards for the NEOs as of the end of Fiscal 2020. At the consummation of the Business Combination, each outstanding equity award reflected in the table below was equitably adjusted in accordance with the terms of the Business Combination Agreement and the 2015 EIP. The amounts set forth in the table do not reflect these adjustments. For additional details regarding the treatment of outstanding equity awards held by the NEOs in connection with the Business Combination, see "Treatment of Equity Awards in Connection with the Business Combination" below.

OUTSTANDING EQUITY AWARDS AT 2020 FISCAL YEAR END(1)

	Option Awards					Stock Awards	
Name	Grant Date	Numbers of Securities Underlying Unexercised Options (#) Exercisable	Numbers of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Matthew Gline	4/20/2016	80,000	—	$ 11.87	4/19/2026	—	—
	5/21/2018	49,856	29,152(2)	$ 23.36	5/20/2028	—	—
	5/20/2019	—	—	—	—	250,000(3)	9,625,000(3)
	3/26/2020		466,035(4)	$ 37.10	3/31/2026	—	—
	3/26/2020		776,725(4)	$ 37.10	3/31/2026	—	—
	3/26/2020		466,035(5)	$ 18.70(6)	3/31/2026	—	—
	3/26/2020		776,725(5)	$ 33.63(6)	3/31/2026	—	—
	5/20/2020	—	300,000(2)	$ 38.23	5/19/2030	—	—
Eric Venker	11/20/2017	74,400	14,564(2)	$ 21.80	11/19/2027	—	—
	5/21/2018	12,510	11,652(2)	$ 23.36	5/20/2028	—	—
	5/20/2019	45,840	54,160(2)	$ 32.07	5/19/2029	—	—
	3/26/2020	—	403,897(4)	$ 46.38	3/31/2026	—	—
	5/20/2020	—	150,000(2)	$ 38.23	5/19/2030	—	—
	5/20/2020	—	—	—	—	150,000(3)	5,775,000(3)

	Option Awards					Stock Awards	
Name	Grant Date	Numbers of Securities Underlying Unexercised Options (#) Exercisable	Numbers of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Benjamin Zimmer	12/30/2015	405	—	$ 14.96	12/29/2025	—	—
	5/20/2016	1,512	—	$ 11.60	5/19/2026	—	—
	5/20/2019	229,170	270,830(2)	$ 32.07	5/19/2029	—	—
	5/20/2019	—	—	—	—	250,000(3)	9,625,000(3)
	3/26/2020	—	62,138(4)	$ 37.10	3/31/2026	—	—
	3/26/2020	—	144,545(4)	$ 40.31	3/31/2026	—	—
	3/26/2020	—	62,138(5)	$ 33.63(6)	3/31/2026	—	—
	5/20/2020	—	210,000(2)	$ 38.23	5/19/2030	—	—
Vivek Ramaswamy	3/26/2020	—	4,126,118(4)	$ 37.10	3/31/2026	—	—
	3/26/2020	—	3,343,002(4)	$ 37.10	3/31/2026	—	—
	3/26/2020	—	599,380(4)	$ 40.31	3/31/2026	—	—
	3/26/2020	—	2,021,411(4)	$ 46.38	3/31/2026	—	—
	3/26/2020	—	3,343,002(5)	$ 18.70(6)	3/31/2026	—	—
	3/26/2020	—	4,126,118(5)	$ 33.63(6)	3/31/2026	—	—

(1) Pursuant to the terms of the Business Combination Agreement, effective as of the closing of the Business Combination on September 30, 2021, outstanding equity awards were adjusted as follows: (i) each share subject to an outstanding Roivant option was multipled by the exhchange ratio of 2.9262:1 (the "Exchange Ratio"), rounded down to the nearest whole share, and the per share exercise price was divided by the Exchange Ratio, rounded up to the nearest whole cent, (ii) each share subject to an outstanding and unvested RSU was multiplied by the Exchange Ratio, rounded down to the nearest whole share, and (iii) each share subject to a capped value appreciation right ("CVAR") was multipled by the Exchange Ratio, rounded down to the nearest whole share, and the per share hurdle price, "knock-in" price and value cap price, as applicable, was divided by the Exchange Ratio, rounded up to the nearest whole cent, as described further below under "Treatment of Equity Awards in Connection with the Business Combination." The numbers in the table reflect the share numbers outstanding as of March 31, 2021 and do not reflect these adjustments that occurred in connection with the closing of the Business Combination on September 30, 2021. However, on September 30, 2021, these numbers were all adjusted pursuant to the Business Combination Agreement.

(2) Reflects the grant of nonqualified stock options to purchase Common Shares outstanding under the 2015 EIP that vest and become exercisable as follows: (i) 25% of the stock options vest and become exercisable on the first anniversary of the vesting commencement date and (ii) the remaining 75% vest in 36 successive equal monthly installments thereafter, in each case, subject to the holder's continuous service through the applicable vesting date. For stock options held by Messrs. Gline and Venker that were granted in 2017 or 2018, immediately prior to (and contingent upon) the occurrence of a "change in control" (as defined in the 2015 EIP), the stock options will become fully vested. For stock options held by the NEOs that were granted after 2018, in the event the NEO's employment is involuntarily terminated without "cause" (as defined in the 2015 EIP and the applicable award agreement) within 12 months following the consummation of a "change in control," the stock options will become fully vested.

(3) Reflects the grant of RSUs outstanding under the 2015 EIP that vest upon the satisfaction of both a "service requirement" and a "liquidity event requirement." The service requirement applicable to the RSUs is satisfied as follows: (i) 25% of the RSUs satisfy the service requirement on the first anniversary of the vesting commencement date and (ii) the remaining 75% of the RSUs satisfy the service requirement in 36 successive equal monthly installments thereafter, in each case, subject to the holder's continuous service through the applicable vesting date. The liquidity event requirement will be satisfied upon the first to occur of a "change in control" or "initial public offering" of Roivant (as defined in the 2015 EIP and the

applicable award agreement) prior to the expiration date of the RSUs, which is eight years from the grant date. If the liquidity event requirement is not satisfied before the expiration date, the RSUs will be forfeited. The number of RSUs reflected in the table above reflects full attainment of the liquidity event requirement, which was satisfied on the closing of the Business Combination. The market value of the RSUs reflected in the table above is based on a share price of $38.50 per share, the fair market value of Common Shares as of March 31, 2021. In the event the NEO's employment is involuntarily terminated for any reason other than for "cause" within 12 months following the consummation of a "change in control," the RSUs will become fully vested.

(4) Reflects the grant of nonqualified performance-based stock options to purchase Common Shares outstanding under the 2015 EIP ("Performance Options") that vest and become exercisable upon the satisfaction of both a "service requirement" and a "liquidity event requirement." The service requirement applicable to the Performance Options is satisfied as follows: (i) 25% of the Performance Options satisfy the service requirement on December 27, 2020 and (ii) the remaining 75% of the Performance Options satisfy the service requirement in 36 successive equal monthly installments thereafter, in each case, subject to the holder's continuous service through the applicable vesting date. The liquidity event requirement will be satisfied upon the first to occur of a "change in control" or "public listing" of Roivant (as defined in the 2015 EIP and the applicable award agreement) prior to the expiration date of the Performance Options. If the liquidity event requirement is not satisfied before the expiration date, the Performance Options will be forfeited. The number of Performance Options reflected in the table above reflects full attainment of the liquidity event requirement, which was satisfied on the closing of the Business Combination.

(5) Reflects the grant of CVARs with respect to Common Shares outstanding under the 2015 EIP that vest upon the satisfaction of both a "service requirement" and a "liquidity event requirement." The service requirement applicable to the CVARs is satisfied as follows: (i) 25% of the CVARs satisfy the service requirement on December 27, 2020 and (ii) the remaining 75% of the CVARs satisfy the service requirement in 36 successive equal monthly installments thereafter, in each case, subject to the holder's continuous service through the applicable vesting date. The liquidity event requirement will be satisfied upon the first to occur of a "change in control" or "public listing" of Roivant (as defined in the 2015 EIP and the applicable award agreement) prior to the expiration date of the CVARs. If the liquidity event requirement is not satisfied before the expiration date, the CVARs will be forfeited. Upon vesting, the CVARs will entitle the holder to a payment equal to the product of (i) the number of vested CVARs *multiplied by* (ii) the excess (if any) of (A) the fair market value of a Common Share as of the relevant date of determination (capped at $37.10 per share) *over* (B) the applicable hurdle price (as described in the footnote 5 below) (the "CVAR Amount"). However, for CVARs with a hurdle price of $18.70 per share, no CVAR Amount will be payable in respect of vested CVARs if the fair market value of a Common Share is less than $26.90 per share as of the relevant date of determination (the "knock-in condition"); instead, such CVARs will remain outstanding unless and until the knock-in condition is satisfied as of any applicable measurement date thereafter before the expiration date of the CVARs. Once payable, the CVARs will be settled in a number of Common Shares determined by dividing (i) the applicable CVAR Amount by (ii) the fair market value of a Common Share as of the applicable payment date. The number of CVARs reflected in the table above reflects full attainment of the liquidity event requirement, which was satisfied on the closing of the Business Combination.

(6) This amount reflects the per share hurdle price applicable to this award of CVARs.

Employment Arrangements

Matthew Gline

Mr. Gline is party to an employment agreement with RSI, dated May 14, 2021, which provides for at-will employment and no specified term of employment. Pursuant to Mr. Gline's employment agreement, Mr. Gline's annual base salary is $725,000, which is subject to adjustment at the discretion of our board of directors or the compensation committee thereof. In addition, Mr. Gline is eligible to receive a discretionary annual performance bonus, with a target annual bonus equal to 100% of his annual base salary. The actual amount of any annual

bonus will be based on an assessment by the compensation committee of our board of directors of Mr. Gline's performance, as well as business conditions at the company. Mr. Gline will also be eligible to receive discretionary periodic or annual equity incentive awards, based on Mr. Gline's performance and business conditions at the company, as determined in the sole discretion of the compensation committee of our board of directors. Mr. Gline is also entitled to participate in the employee benefit plans and programs (including any medical, dental, vision, life and disability insurance benefit plans and 401(k) plan) as provided by RSI to similarly situated full-time employees from time to time.

Pursuant to Mr. Gline's employment agreement, in the event Mr. Gline's employment is terminated by RSI without "cause" (other than due to Mr. Gline's death or "disability") or Mr. Gline resigns for "good reason" (each as defined in Mr. Gline's employment agreement), then, subject to Mr. Gline's timely execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, Mr. Gline will be entitled to receive (i) continued payment of his base salary for 12 months following the date of his termination, payable in accordance with RSI's customary payroll procedures, (ii) an amount equal to his target annual bonus for the year of termination, payable in 12 equal monthly installments following the date of his termination and (iii) monthly reimbursement of COBRA premiums (less active employee rates) for 12 months following the date of his termination (or, if earlier, until the date Mr. Gline becomes eligible for coverage under a subsequent employer's group health insurance plan).

Pursuant to Mr. Gline's employment agreement, in the event of a termination of Mr. Gline's employment due to his death or disability, to the extent not already provided under the applicable award agreements and subject to the execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, all service-based vesting conditions with respect to 50% of Mr. Gline's then-outstanding equity awards granted prior to March 31, 2021 will be immediately waived, and will thereafter otherwise remain subject to the other existing terms and conditions of such awards (including the achievement of any applicable performance-based vesting conditions and any liquidity event vesting conditions, as the case may be). In addition, pursuant to the terms of Mr. Gline's outstanding Performance Options and CVARs granted prior to March 31, 2021, in the event Mr. Gline's employment is terminated by RSI without cause, due to Mr. Gline's death or disability or Mr. Gline resigns for any reason (with or without good reason), subject to Mr. Gline's timely execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, all service-based vesting conditions with respect to 50% of Mr. Gline's then-outstanding Performance Options and CVARs will be immediately waived, and will thereafter otherwise remain subject to the other existing terms and conditions of such awards (including the achievement of any applicable performance-based vesting conditions and any liquidity event vesting conditions, as the case may be).

Eric Venker

Dr. Venker is party to an employment agreement with RSI, dated May 14, 2021, which provides for at-will employment and no specified term of employment. Pursuant to Dr. Venker's employment agreement, Dr. Venker's annual base salary is $620,000, which is subject to adjustment at the discretion of the compensation committee of our board of directors. In addition, Dr. Venker is entitled to receive quarterly board fees in the amount of $3,125 per fiscal quarter (or such other amount as may be determined by Roivant) in respect of each private company affiliate of Roivant based in the United Kingdom for which Dr. Venker serves as a member of the board of directors. Dr. Venker's annual base salary is reduced by the aggregate annual amount of such board fees payable to Dr. Venker. Dr. Venker is also eligible to receive a discretionary annual performance bonus, with a target annual bonus equal to 55% of his annual base salary (without giving effect to any reductions in such base salary for board fees). The actual amount of any annual bonus will be based on an assessment by the compensation committee of our board of directors of Dr. Venker's performance, as well as business conditions at the company. Dr. Venker will also be eligible to receive discretionary periodic or annual equity incentive awards, based on Dr. Venker's performance and business conditions at the company, as determined in the sole discretion of the compensation committee of our board of directors. Dr. Venker is also entitled to participate in the employee benefit plans and programs (including any medical, dental, vision, life and disability insurance benefit plans and 401(k) plan) as provided by RSI to similarly situated full-time employees from time to time.

Pursuant to Dr. Venker's employment agreement, in the event Dr. Venker's employment is terminated by RSI without "cause" (other than due to Dr. Venker's death or "disability") or Dr. Venker resigns for "good reason" (each as defined in Dr. Venker's employment agreement), then, subject to Dr. Venker's timely execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, Dr. Venker will be entitled to receive (i) continued payment of his base salary (without giving effect to any reductions in such base salary for board fees) for 12 months following the date of his termination, payable in accordance with RSI's customary payroll procedures, (ii) an amount equal to his target annual bonus for the year of termination, payable in 12 equal monthly installments following the date of his termination and (iii) monthly reimbursement of COBRA premiums (less active employee rates) for 12 months following the date of his termination (or, if earlier, until the date Dr. Venker becomes eligible for coverage under a subsequent employer's group health insurance plan).

In addition, in the event of a termination of Dr. Venker's employment due to his death or disability, subject to the execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, all service-based vesting conditions with respect to 50% of Dr. Venker's then-outstanding equity awards granted prior to March 31, 2021 will be immediately waived, and will thereafter otherwise remain subject to the other existing terms and conditions of such awards (including the achievement of any applicable performance-based vesting conditions and any liquidity event vesting conditions, as the case may be).

Vivek Ramaswamy

Mr. Ramaswamy is party to an employment agreement with RSI, dated May 14, 2021, which provides for at-will employment and no specified term of employment. Pursuant to Mr. Ramaswamy's employment agreement, Mr. Ramaswamy's annual base salary is $350,000, which is subject to increase at the discretion of our board of directors. In addition, Mr. Ramaswamy is entitled to receive an annual bonus for each fiscal year of employment, with a target annual bonus equal to 100% of his annual base salary. Mr. Ramaswamy is also entitled to participate in the employee benefit plans and programs provided by RSI to its employees from time to time.

Pursuant to Mr. Ramaswamy's employment agreement, in the event Mr. Ramaswamy's employment is terminated by RSI without "cause" or Mr. Ramaswamy resigns for "good reason" (each as defined in Mr. Ramaswamy's employment agreement), then, subject to Mr. Ramaswamy's timely execution and non-revocation of a release of claims, Mr. Ramaswamy will be entitled to receive (i) continued payment of his base salary for two years following the date of his termination, payable in accordance with RSI's customary payroll procedures, (ii) a lump sum payment equal to the average of his target annual bonus for the three years prior to the termination date and (iii) monthly payment (or reimbursement) of COBRA premiums (less active employee rates) for 18 months following the date of his termination (or, if earlier, until the date Mr. Ramaswamy becomes eligible for coverage under a subsequent employer's group health insurance plan).

In addition, with respect to equity awards granted to Mr. Ramaswamy prior to March 31, 2021, subject to his timely execution and non-revocation of a release of claims, (i) in the event Mr. Ramaswamy's employment is terminated by RSI without cause, by Mr. Ramaswamy for good reason or by mutual agreement between him and RSI, then all service-based vesting conditions with respect to 100% of such awards then outstanding will be immediately waived and (ii) in the event Mr. Ramaswamy's employment is terminated due to his death or disability, then all service-based vesting conditions with respect to 50% of such awards then outstanding will be immediately waived, in each case provided that all such awards will thereafter otherwise remain subject to the other existing terms and conditions of such awards (including the achievement of any applicable performance-based vesting conditions and any liquidity event vesting conditions, as the case may be).

Benjamin Zimmer

In connection with the transfer of Mr. Zimmer's employment to a newly-formed subsidiary of Roivant on November 10, 2021, Mr. Zimmer entered into a separation agreement pursuant to which Mr. Zimmer is entitled

to receive, subject to his execution and non-revocation of a release of claims, (i) continued vesting of his outstanding Roivant equity awards through June 30, 2023, subject to his continued employment with the newly-formed subsidiary (or, if applicable, RSI) (the "Additional Vesting Period"), (ii) in the event of a termination of Mr. Zimmer's employment during the Additional Vesting Period due to his death or disability, subject to his execution and non-revocation of a release of claims and continued compliance with applicable restrictive covenants, vesting of all service-based vesting conditions with respect to 50% of Mr. Zimmer's then-outstanding Roivant equity awards granted prior to March 31, 2021, which awards will otherwise remain subject to all of their existing terms and (iii) the annual performance bonus for which Mr. Zimmer was eligible in the performance review cycle ending March 31, 2022, prorated for the period from April 1, 2021 to November 10, 2021, subject to his continued employment with the newly-formed subsidiary on the date the bonus is to be paid (on or before April 30, 2022).

On December 21, 2021, in recognition of his role in the completion of Datavant's merger with Ciox Health, RSI provided a bonus award letter to Mr. Zimmer, which provides for a one-time, lump sum cash bonus of $1,000,000 on or before December 31, 2021, subject to Mr. Zimmer's continued employment with Roivant or one of its subsidiaries in good standing through the applicable payment date. The award letter also provides for a discretionary cash bonus in an amount equal to 0.5% of the net cash proceeds actually received by Roivant upon the occurrence of one or more qualifying realization events relating to Roivant's interest in Datavant (or the holding company thereof). This discretionary realization bonus is payable within 60 days following the date Roivant receives the corresponding net proceeds from the applicable qualifying realization event, subject to Mr. Zimmer's (i) continued employment with Roivant or one of its subsidiaries in good standing through such payment date and (ii) execution and nonrevocation of a release of claims.

Restrictive Covenants

The employment agreements for each of the NEOs provide for customary non-competition and non-solicitation covenants that apply during the term of the NEO's employment and at least 12 months thereafter. In addition, the employment agreements contain standard confidentiality and non-disparagement provisions that apply during the term of the NEO's employment and perpetually thereafter.

Benefit Plans

Roivant's NEOs participate in employee benefit programs available to its employees generally, including health, dental and vision insurance and a tax-qualified 401(k) plan maintained by RSI. Neither Roivant nor its subsidiaries maintained any executive-specific benefit or perquisite programs in Fiscal 2020.

Under RSI's 401(k) plan, eligible employees (including the NEOs) are able to defer up to 90% of their eligible compensation subject to applicable annual limits under the Internal Revenue Code. All participants are 100% vested in their deferrals when contributed. Currently, RSI provides matching contributions for employees' pre-tax contributions on a dollar-for-dollar basis up to $8,550 annually per employee. These matching contributions generally become vested after two years of service by an employee.

Employee Stock Purchase Plan

In connection with the Business Combination, our board of directors approved and adopted the Roivant Sciences Ltd. 2021 Employee Stock Purchase Plan (the "ESPP").

The following summary of the material terms of the ESPP does not purport to be complete and is qualified in its entirety by the terms of the ESPP, a form of which is filed as an exhibit to the registration statement to which this prospectus forms a part.

Purpose

The ESPP is intended to provide employees of Roivant and participating subsidiaries with an opportunity to acquire a proprietary interest in Roivant through the purchase of shares at a discount through payroll deductions.

Administration

The ESPP is administered by the compensation committee of our board of directors, which may delegate its authority to one or more officers of Roivant and to one or more committees of the board of directors.

Our compensation committee has the authority to construe and interpret the ESPP, prescribe, amend and rescind rules relating to the ESPP's administration and take any other actions necessary or desirable for the administration of the ESPP and correct any defect or supply any omission or reconcile any inconsistency or ambiguity in the ESPP.

Authorized Shares

Subject to certain adjustments as described below, the aggregate number of Common Shares that initially may be issued under the ESPP will be 13,900,000. In addition, on the first day of each fiscal year following the effective date of the ESPP, the number of Common Shares reserved for issuance under the ESPP will automatically increase by an amount equal to the least of (i) 13,900,000 Common Shares, (ii) 1% of the Common Shares outstanding as of the last day of the immediately preceding fiscal year and (iii) such number of Common Shares as determined by our board of directors in its discretion. The maximum number of Common Shares that may be issued under the ESPP is 147,447,650 Common Shares (subject to adjustment as noted under "*–Adjustments*" below).

Eligibility and Participation

Any employee of Roivant or a participating subsidiary who has completed (or who has been credited with) at least three (3) months of continuous employment or service with Roivant or any participating subsidiary and is customarily employed for at least twenty (20) hours per week may participate in the ESPP. The compensation committee may exclude from participation in the ESPP any employees who are "highly compensated employees," or any sub-set of such "highly compensated employees." The compensation committee may also exclude any employees located outside of the United States to the extent permitted under Section 423 of the Code.

Offering Periods

The ESPP will be implemented through a series of six-month offering periods (each, an "Offering Period"), expected to commence on January 1 and July 1 of each year. The compensation committee has the authority to change the duration and start and end dates of the Offering Periods.

Adjustments

In the event that any dividend or other distribution (whether in the form of cash, Common Shares, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, amalgamation, split-up, spin-off, combination, repurchase or exchange of Common Shares or other securities of Roivant, or other change in Roivant's structure affecting the Common Shares occurs, then in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the ESPP, the compensation committee will, in such manner as it deems equitable adjust the number of Common Shares and class of Common Shares that may be delivered under the ESPP, adjust the purchase price per Common Share and the number of Common Shares covered by each outstanding option under the ESPP; and adjust the Common Share numerical limits.

Term; Amendment and Termination

The ESPP has a 10 year term.

The compensation committee has the authority to amend, suspend or terminate the ESPP at any time and for any reason. If the ESPP is terminated, the compensation committee may elect either to terminate all outstanding offering periods either immediately or once Common Shares have been purchased on the next purchase date; or permit offering periods to expire in accordance with their terms. If an offering period is terminated before its scheduled expiration, all amounts that have not been used to purchase Common Shares will be returned to participants.

Equity Incentive Compensation Plans

Amended and Restated 2015 Equity Incentive Plan

Roivant maintains the Amended and Restated Roivant Sciences Ltd. 2015 Equity Incentive Plan (the "2015 EIP"), which provides for the discretionary grant of equity awards to eligible participants. Effective at the consummation of the Business Combination, the 2015 EIP was terminated and no further awards will be granted under the 2015 EIP. All awards outstanding under the 2015 EIP will remain subject to the terms of the 2015 EIP and the applicable award agreement, subject to adjustments made at the closing of the Business Combination. There are currently awards of nonqualified stock options (including Performance Options), RSUs and CVARs outstanding under the 2015 EIP. The following sets forth a summary of certain material features of the 2015 EIP, and is qualified in its entirety by the text of the 2015 EIP, a form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Purpose

The 2015 EIP is intended to help Roivant secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Roivant and its affiliates and provide a means by which the eligible recipients may benefit from increases in value of Roivant's shares.

Administration

The 2015 EIP is administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of its directors (referred to collectively as the "plan administrator").

Our board of directors has the authority to, among other things and subject to the limitations imposed under the 2015 EIP, stock exchange rules and other applicable law, determine the eligible participants to be granted awards and the terms and conditions of such awards; construe and interpret the 2015 EIP and awards granted thereunder and to establish, amend and revoke rules for the administration of the 2015 EIP and awards granted thereunder; settle all controversies regarding the 2021 EIP and awards granted under it; accelerate, in whole or in part, the time at which an award may be exercised or vest; approve forms of award agreements for use under the 2015 EIP; amend the terms of any one or more awards; effect, with the consent of any adversely affected participant, the reduction of the exercise price of any outstanding award, the cancellation of any outstanding award and the grant in substitution therefor of a new award, cash and/or other valuable consideration, or any other action that is treated as a repricing under generally accepted accounting principles; and exercise such powers and perform such acts as our board of directors deems necessary or expedient to promote the best interests of Roivant.

To the extent permitted by applicable law, our board of directors may also delegate its authority under the 2015 EIP to one or more officers to designate employees to be recipients of awards and to determine the number of shares to be granted pursuant to awards, subject to specified limits.

Eligibility

Employees, consultants and directors of Roivant and certain of its affiliates are eligible to receive awards under the 2015 EIP to the extent our board of directors determines that the grant of such award furthers the purpose of the 2015 EIP (as described above).

Awards

The 2015 EIP provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock awards.

As of September 30, 2021, there were 142,080,122 Common Shares underlying outstanding awards under the 2015 EIP (giving effect to the adjustments noted below which occurred in connection with the Business Combination). Following the consummation of the Business Combination, all awards outstanding under the 2015 EIP remain subject to the terms of the 2015 EIP and the applicable award agreement, subject to the adjustments made at the closing of the Business Combination as described in more detail below. No further awards will be granted under the 2015 EIP.

Capitalization Adjustments

In the event there is a specified type of change in Roivant's capital structure, such as a merger, consolidation, reorganization, recapitalization, reincorporation, share dividend, dividend in property other than cash, large nonrecurring cash dividend, share split, reverse share split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, appropriate adjustments will be made to the class and maximum number of shares reserved for issuance under the 2015 EIP, the class and maximum number of shares that may be issued upon the exercise of incentive stock options, and the class and number of shares and exercise price, strike price, knock-in price measure, threshold, target or maximum price measure or other price measure, if applicable, of all outstanding awards.

Change in Control

The 2015 EIP provides that, in the event of a change in control of Roivant (as described below), our board of directors may take one or more of the following actions with respect to outstanding awards, contingent upon the closing or completion of the change in control:

- arrange for the assumption, continuation or substitution of the award by the successor or acquiring corporation (or its parent);
- arrange for lapse of, or the assignment to the successor or acquiring corporation (or its parent) of, any reacquisition or repurchase rights held by Roivant;
- accelerate the vesting (in whole or in part) of the award and provide for its termination prior to the effective time of the change in control;
- cancel the award prior to the effective time of the change in control in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the award; or
- make a payment, in such form as determined by the Roivant, equal to the excess, if any, of the value of the property that would have been received if such award was exercised immediately prior to the effective time of the change in control over any exercise price payable (which may be $0 if the value of the property is equal to or less than the exercise price), which such payments may be delayed to the same extent that payment of consideration to Roivant shareholders in connection with the change in control is delayed as a result of escrows, earn outs, holdbacks or any other contingencies).

Our board of directors is not obligated to treat all awards or portions of awards in the same manner. Our board of directors may take different actions with respect to the vested and unvested portions of an award.

A "change in control" is generally defined under the 2015 EIP to include the following:

- a transaction or series of related transactions in which a person, or a group of related persons, acquires from Roivant shares representing a majority of the voting power or economic interests of Roivant;
- a merger, amalgamation or scheme of arrangement in which Roivant is a constituent party and Roivant issues shares pursuant to such transaction, except in circumstances where, Roivant shares outstanding immediately prior to such transaction continue to represent, or are converted into or exchanged for shares that represent, immediately following such transaction, at least a majority of the voting power of the surviving or amalgamated corporation or Roivant (or, if such surviving or amalgamated corporation or Roivant is a wholly owned subsidiary of another corporation immediately following such transaction, the parent corporation of such surviving or amalgamated corporation or Roivant);
- the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by Roivant or any subsidiary of Roivant of all or substantially all the assets of Roivant and its subsidiaries taken as a whole; or
- the sale or disposition (whether by merger, amalgamation, scheme of arrangement or otherwise) of one or more subsidiaries of Roivant if substantially all of the assets of Roivant and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of Roivant.

Plan Amendment, Suspension or Termination

Our board of directors has the authority to amend, suspend, or terminate the 2015 EIP at any time; *provided* that such action does not materially impair the existing rights of any participant without such participant's written consent. No awards may be granted under the 2015 EIP while the 2015 EIP is suspended or after it is terminated.

2021 Equity Incentive Plan

In connection with the Business Combination, our board of directors approved and adopted the Roivant Sciences Ltd. 2021 Equity Incentive Plan (the "2021 EIP"). The following sets forth a summary of certain material features of the 2021 EIP, and is qualified in its entirety by the text of the 2021 EIP, a form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Purpose

The 2021 EIP is intended to help Roivant secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Roivant and its affiliates and provide a means by which the eligible recipients may benefit from increases in value of Roivant's shares.

Administration

The 2021 EIP is administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of its directors (referred to collectively as the "plan administrator").

Our board of directors has the authority to, among other things and subject to the limitations imposed under the 2021 EIP, stock exchange rules and other applicable law: determine the eligible participants to be granted awards and the terms and conditions of such awards; construe and interpret the 2021 EIP and awards granted thereunder; settle all controversies regarding the 2021 EIP and awards granted under it; accelerate, in whole or in part, the time at which an award may be exercised or vest; approve forms of award agreements for use under the 2021 EIP; amend the terms of any one or more awards; effect, with the consent of any adversely affected participant, the reduction of the exercise price of any outstanding award, the cancellation of any outstanding award and the grant in substitution therefor of a new award, cash and/or other valuable consideration, or any

other action that is treated as a repricing under generally accepted accounting principles; and exercise such powers, perform such acts and make any other determinations as our board of directors deems necessary, expedient or desirable to promote the best interests of Roivant and for due compliance with applicable law, stock market or exchange rules and regulations or accounting or tax rules and regulations.

To the extent permitted by applicable law, our board of directors may also delegate its authority under the 2021 EIP to one or more officers to designate employees to be recipients of awards and to determine the number of shares to be granted pursuant to awards, subject to specified limits.

Authorized Shares

Subject to certain adjustments as described below, the aggregate number of Common Shares that initially may be issued under the 2021 EIP is 69,300,000. In addition, on the first day of each fiscal year of Roivant following the effective date of the 2021 EIP and prior to the termination of the 2021 EIP, the number of Common Shares reserved for issuance under the 2021 EIP will automatically increase by an amount equal to the lesser of (i) 5% of the Common Shares outstanding as of the last day of the immediately preceding fiscal year and (ii) such number of Common Shares as determined by our board of directors in its discretion. The maximum number of Common Shares that may be issued pursuant to the exercise of incentive stock options under the 2021 EIP is equal to the initial share reserve under the 2021 EIP as described above.

The maximum number of Common Shares subject to any awards granted under the 2021 EIP during any fiscal year to any non-employee director, taken together with any cash fees paid by Roivant to such director during such fiscal year, will not exceed $750,000 (or $1,000,000 for such director's first fiscal year of service on our board of directors) in total value.

Common Shares subject to awards granted under the 2021 EIP that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of Common Shares available for issuance under the 2021 EIP. Additionally, Common Shares issued pursuant to awards under the 2021 EIP that are repurchased by Roivant or are forfeited, as well as Common Shares reacquired by Roivant as consideration for the exercise or purchase price of an award or to satisfy tax withholding obligations related to an award, will become available for future grant under the 2021 EIP.

Eligibility

Employees, consultants and directors of Roivant and certain of its affiliates (including individuals who has accepted an offer of employment or service from Roivant and certain of its affiliates) are eligible to receive awards under the 2021 EIP to the extent our board of directors determines that the grant of such award furthers the purpose of the 2021 EIP (as described above).

Awards

The 2021 EIP provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock awards.

Capitalization Adjustments

In the event there is a specified type of change in Roivant's capital structure, such as a merger, consolidation, amalgamation, reorganization, recapitalization, reincorporation, share dividend, dividend in property other than cash, large nonrecurring cash dividend, share split, reverse share split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, appropriate adjustments will be made to the class and maximum number of shares reserved for issuance under the 2021 EIP, the class and maximum number of shares that may be issued upon the exercise of

incentive stock options, and the class and number of shares and exercise price, strike price, knock-in price measure, threshold, target or maximum price measure or other price measure, if applicable, of all outstanding awards.

Change in Control

The 2021 EIP provides that in the event of a change in control of Roivant (as described below), our board of directors may take one or more of the following actions with respect to outstanding awards upon the closing of the change in control:

- arrange for the assumption, continuation or substitution of the award by the successor or acquiring corporation (or its parent);
- arrange for the assignment of any reacquisition or repurchase rights held by Roivant to the successor or acquiring corporation (or its parent);
- accelerate the vesting of the award and provide for its termination prior to the effective time of the change in control;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by Roivant;
- determine the level of attainment of any performance conditions applicable to the award;
- cancel the award prior to the effective time of the change in control in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the award; or
- cancel the award in exchange for a payment, in such form as determined by our board of directors, equal to the excess, if any, of the value of the property that would have been received if such award was exercised immediately prior to the effective time of the change in control over any exercise price payable (which may be $0 if the value of the property is equal to or less than the exercise price), which such payments may be delayed to the same extent that payment of consideration to Roivant shareholders in connection with the change in control is delayed as a result of escrows, earn outs, holdbacks or any other contingencies).

Our board of directors is not obligated to treat all awards or portions of awards in the same manner. Our board of directors may take different actions with respect to the vested and unvested portions of an award.

A “change in control” is generally defined under the 2021 EIP to include the following:

- any person, entity or group is (or becomes during any 12-month period) the beneficial owner of 50% or more of the total voting power of Roivant shares;
- a change in the composition of our board of directors such that, during any 12-month period, the individuals who, as of the beginning of such period, constitute our board of directors (“Existing Board”) cease for any reason to constitute a majority of our board of directors (with any individuals whose appointment to our board of directors was approved by a vote of at least a majority of the members of the Existing Board being considered a member of the Existing Board);
- the consummation of a merger, amalgamation or consolidation of Roivant with any another corporation or entity, or the issuance of voting securities in connection with such a transaction pursuant to applicable stock exchange requirements, except in circumstances where, immediately following such transaction, the voting securities of Roivant continue to represent 50% or more of the total voting power and total fair market value of the surviving entity or its parent; or
- the sale or disposition by Roivant of all or substantially all of its assets in which any person, entity or group acquires (or has acquiring during a 12-month period) more than 50% of the total gross fair market value of all of the assets of Roivant.

Clawback

Awards granted under the 2021 EIP are subject to recoupment in accordance with any clawback policy that Roivant is required to adopt pursuant to the listing standards of any national securities exchange or association on which Roivant's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, our board of directors may impose such other clawback, recovery or recoupment provisions in an award agreement as our board of directors determines necessary or appropriate.

Term; Plan Amendment, Suspension or Termination

The 2021 EIP has a 10 year term. Our board of directors has the authority to amend, suspend, or terminate the 2021 EIP at any time; *provided* that such action does not materially impair the existing rights of any participant without such participant's written consent. Unless terminated sooner by our board of directors, the 2021 EIP will automatically terminate on the day before the tenth anniversary of the effective date of the 2021 EIP. No awards may be granted under the 2021 EIP while the 2021 EIP is suspended or after it is terminated.

Treatment of Equity Awards in Connection with the Business Combination

In connection with the Business Combination, equity incentive awards then-outstanding under the 2015 EIP were equitably adjusted in accordance with the terms of the 2015 EIP and the Business Combination Agreement. Specifically, on the date of the consummation of the Business Combination:

- each outstanding Roivant option, whether vested or unvested, was adjusted as follows: (i) the number of post-closing Common Shares subject to such Roivant option equals the product of (a) the number of Common Shares subject to the Roivant option before such adjustment, *multiplied by* (b) the "exchange ratio," rounded down to the nearest whole share, and (ii) the per share exercise price of such Roivant option equals the quotient of (x) the per share exercise price at which the Roivant option was exercisable before such adjustment, *divided by* (y) the exchange ratio, rounded up to the nearest whole cent. Following such adjustment, the Roivant options otherwise remain subject to the same terms and conditions (including the applicable vesting, expiration and forfeiture provisions) as applied before such adjustment.
- each outstanding and vested Roivant RSU was adjusted by multiplying (i) the number of Common Shares that were subject to the vested Roivant RSU before the adjustment *by* (ii) the exchange ratio, *minus* (iii) that number of post-closing Common Shares with a fair market value equal to all required withholding taxes due upon settlement of such vested Roivant RSU, which such vested Roivant RSUs will be settled (including as to timing) in accordance with the terms of the 2015 EIP and the applicable award agreement thereunder.
- each outstanding unvested Roivant RSU was adjusted as follows: the number of post-closing Common Shares subject to such unvested Roivant RSU is equal to the product of (i) the number of Common Shares that were subject to the unvested Roivant RSU before the adjustment *multiplied by* (ii) the exchange ratio, rounded down to the nearest whole share. Following such adjustment, the unvested Roivant RSUs otherwise remain subject to the same terms and conditions (including the applicable vesting, expiration and forfeiture provisions) as applied before such adjustment.
- each outstanding Roivant CVAR, whether vested or unvested, was adjusted as follows: (i) the number of post-closing Common Shares subject to such CVAR is equal to the product of (a) the number of Common Shares that were subject to the Roivant CVAR before the adjustment, *multiplied by* (b) the exchange ratio, rounded down to the nearest whole share, and (ii) the per share hurdle price, "knock-in" price and value cap price, as applicable, of such CVAR is equal to the quotient of (x) the per share hurdle price, "knock-in" price and value cap price, as applicable, applicable to the Roivant CVAR before the adjustment, *divided by* (y) the exchange ratio, rounded up to the nearest whole cent.

Following such adjustment, the Roivant CVARs otherwise remain subject to the same terms and conditions (including the applicable vesting, expiration and forfeiture provisions) as applied before such adjustment.

Director Compensation

Fiscal 2020 Director Compensation Table

The following table sets forth information regarding the annual cash retainer paid to directors of our board of directors in respect of Fiscal 2020. Roivant did not grant equity incentive compensation to directors in respect of Fiscal 2020.

During Fiscal 2020, only Messrs. Ramaswamy, Lo and Machado were provided compensation for their services on our board of directors. During Fiscal 2020, Mr. Ramaswamy served as both an executive officer and a director of Roivant and his compensation for his service as former executive officer is set forth above in "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Total ($)
Vivek Ramaswamy	$ 150,000	—	$150,000
Andrew Lo	$ 200,000	—	$200,000
Patrick Machado	$ 75,000	—	$ 75,000

(1) Mr. Ramaswamy's equity incentive awards as of March 31, 2021 are set forth above in "Executive Compensation—Outstanding Equity Awards at Fiscal Year End." As of March 31, 2021, each of Messrs. Lo and Machado held the following Roivant equity incentive awards granted under the 2015 EIP:

(a) Dr. Lo holds 236,000 stock options granted on October 20, 2016 with an exercise price of $15.17 per share, all of which were vested and exercisable. Following this grant of stock options, Dr. Lo has not been eligible to receive any other equity compensation for his services on our board of directors.

(b) Mr. Machado holds (i) 58,153 stock options granted on October 20, 2016 with an exercise price of $15.17 per share, all of which were vested and exercisable, (ii) 37,500 stock options granted on December 20, 2017 with an exercise price of $21.72 per share, all of which were vested and exercisable, (iii) 37,500 stock options granted on January 22, 2019 with an exercise price of $32.72 per share, of which 29,172 were vested and exercisable and the remaining will vest and become exercisable in equal monthly installments through the period ending on November 30, 2021, and (iv) 37,500 stock options granted on January 20, 2020 with an exercise price of $37.10 per share, of which 16,668 were vested and exercisable and the remaining will vest and become exercisable in equal monthly installments through the period ending on November 30, 2022.

Annual cash retainers payable to directors are calculated based upon the prorated number of quarterly periods each non-employee director served in their respective capacity as a board and/or committee member in a given fiscal year. Except for Dr. Lo, who is not eligible to receive any expense reimbursement in connection with his service on our board of directors, directors are also eligible to be reimbursed for actual expenses incurred in attending meetings of our board of directors and any of its committees.

Post-Business Combination Director Compensation Program

Our board of directors has also approved a Non-Employee Directors Compensation Policy pursuant to which our non-employee directors will receive compensation for their service on the board of directors, as described below. The compensation payable to our non-employee directors under this policy is subject to the limitations on non-employee director compensation set forth in the 2021 EIP (as described above).

Cash Retainers

Our non-employee directors are entitled to receive annual cash retainers for their service, which are payable in equal quarterly installments as follows:

Role	Retainer
Board Member	$ 40,000
Lead Independent Director	$ 25,000
Board Chair	$ 35,000
Audit Committee Chair	$ 20,000
Audit Committee Member	$ 10,000
Compensation Committee Chair	$ 15,000
Compensation Committee Member	$ 7,500
Nominating and Governance Committee Chair	$ 10,000
Nominating and Governance Committee Member	$ 5,000

Prior to the last day of any fiscal year, a non-employee director may elect that either 50% or 100% of his or her annual cash retainers payable in the following fiscal year be paid in the form of unrestricted Common Shares.

Initial Equity Retainer

Upon a non-employee director's initial commencement of service on our board of directors, each non-employee director will be entitled to receive an initial, one-time award of stock options under the 2021 EIP with an aggregate grant date value of $600,000. The initial option award will vest over a three-year period, with 1/3 vesting on the first anniversary of the applicable vesting commencement date and the remaining portion of the award vesting in 24 equal monthly installments, subject to the non-employee director's continuous service through the applicable vesting date, except that, in the event of a change in control (as defined under the 2021 EIP), such stock options will become fully vested and exercisable.

Annual Equity Retainers

On the date of our annual general meeting of shareholders, each non-employee director (i) who has completed at least three (3) months of continuous service as a non-employee director as of the date of such meeting and (ii) whose term is scheduled to continue at least through the date of the next annual meeting will be entitled to receive (1) an annual award of stock options under the 2021 EIP with an aggregate grant date value of $200,000, and (2) an annual award of restricted stock units under the 2021 EIP with an aggregate grant date value of $200,000. If the non-employee director commences service on our board on a date other than at the annual meeting of shareholders, then they will be entitled to receive a prorated annual equity award on the date of the next annual meeting following his or her start date, if he or she otherwise satisfies the eligibility requirements. Each annual equity award will vest and, if applicable, become exercisable in full on the one-year anniversary of the applicable vesting commencement date, subject to the non-employee director's continuous service through such vesting date, except that, in the event of a change in control, any the annual equity awards will become fully vested and, if applicable, exercisable.

Emerging Growth Company Status

As an emerging growth company, Roivant is exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of Roivant's chief executive officer to the median of the annual total compensation of all of Roivant's employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions occurring during our last three fiscal years or currently proposed, to which (i) Roivant Sciences Ltd. has been a participant, (ii) the amount involved exceeded or will exceed $120,000 and (iii) any of Roivant's directors, executive officers or holders of more than 5% of Roivant's share capital, or any members of their immediate family (collectively "Roivant Related Parties"), had or will have a direct or indirect material interest. The Common Share numbers disclosed in the transactions and/or agreements described below are presented without giving effect to the subdivision of the Common Shares that took place at the closing of the Business Combination.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions meeting these criteria to which we have been or will be a party other than compensation arrangements, which are described where required under "Executive Compensation—Director Compensation" and "Executive Compensation—Post-Business Combination Director Compensation Program."

Transactions with Sumitomo Dainippon Pharma Co., Ltd.

On October 31, 2019, we entered into a transaction agreement with Sumitomo (the "Sumitomo Transaction Agreement"), which closed on December 27, 2019 (the "Sumitomo Closing Date"). Pursuant to the Sumitomo Transaction Agreement, we transferred our entire ownership interest in Myovant, Urovant, Enzyvant, Altavant and Spirovant (collectively "Sumitovant Vants") to a newly formed, wholly-owned entity ("Sumitovant"). Our ownership interest in Sumitovant was then transferred to Sumitomo, such that following the Sumitomo Closing Date, Sumitovant and its subsidiaries, including the Sumitovant Vants, were each directly or indirectly owned by Sumitomo.

Additionally, in connection with the Sumitomo Transaction Agreement, we (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of our ownership interests in six other subsidiaries (Dermavant, Genevant, Lysovant, Metavant, Cytovant and Sinovant (collectively the "Option Vants")), (ii) (a) transferred the proprietary technology platform DrugOme to Sumitomo (for which Roivant retains a perpetual royalty free license for internal use) and (b) licensed the Digital Innovation technology platform to Sumitomo (for which both parties retain ongoing access) and (iii) transferred 26,952,143 of our Common Shares to Sumitomo. On the Sumitomo Closing Date, the Company received approximately $3.0 billion in cash, resulting in a gain of $2.0 billion after taking into account all of the components of the transaction.

Concurrently with the Sumitomo Transaction Agreement, (i) Roivant, Sumitomo and Sumitovant entered into a transition services agreement, whereby each of the parties thereto agreed to provide certain services to one another at cost for a period of time following the Sumitomo Closing Date and (ii) Roivant and Sumitomo entered into a strategic cooperation agreement relating to certain ongoing technology-related collaborations between the parties. Pursuant to the terms of the transition services agreement and strategic cooperation agreement, we billed Sumitovant $1.4 million and $0.2 million, net of amounts billed by Sumitovant to us, respectively, during the years ended March 31, 2021 and 2020 for costs incurred on behalf of Sumitovant.

Additionally, on the Sumitomo Closing Date, Sumitomo deposited $75.0 million of the consideration payable pursuant to the Sumitomo Transaction Agreement in a segregated escrow account for the purpose of fulfilling our indemnification obligations that may become due to Sumitomo. Upon the expiration of the escrow period, being 18 months from the Sumitomo Closing Date, any remaining escrow funds will be disbursed to us.

On the Sumitomo Closing Date, we also entered into an agreement with Sumitomo, pursuant to which we granted Sumitomo a right of first refusal with respect to potential transfers of Roivant's ownership interest in common shares of Sio Gene Therapies (formerly Axovant Gene Therapies) (the "ROFR"). Among other things, such agreement provides that Roivant must promptly deliver notice to Sumitomo if it desires to transfer equity interests of Sio Gene Therapies and provide Sumitomo with an opportunity to make a matching offer for the subject shares in accordance with the terms and conditions set forth therein. The ROFR terminates on October 31, 2024. The ROFR also includes certain notification rights in favor of Sumitomo, in the event Roivant takes certain specified corporate actions.

At the Sumitomo Closing Date, we also entered into a Share Return Agreement (the "Share Return Agreement") with Sumitomo pursuant to which, subject to certain conditions provided therein, if Sumitomo directly or indirectly holds greater than 55.0% of the then issued and outstanding Common Shares of Myovant Sciences Ltd. (the "Requisite Threshold"), Sumitomo shall return to Roivant for no consideration Common Shares, up to a total of 4,243,005 Common Shares, such that Sumitomo directly or indirectly continues to hold Common Shares in excess of the Requisite Threshold.

In connection with the foregoing transactions with Sumitomo, our board of directors approved an exchange and offer to repurchase equity securities for up to $1.0 billion of the proceeds received from Sumitomo. See "—Equity Exchange and Offer to Purchase."

During the years ended March 31, 2021 and 2020, we paid Sumitomo a $1.0 million access fee pursuant to the strategic cooperation agreement.

In May 2021, we entered into an Asset Purchase Agreement with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. ("SPC") (the "Asset Purchase Agreement"). The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire our equity interests in the Option Vants; (ii) we transferred and assigned to SPC all of our intellectual property, development, regulatory and commercialization rights to (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively "Greater China"), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea, and (d) RVT-802 in Greater China and South Korea; (iii) we received a $5 million cash payment; and (iv) Sumitomo entered into an agreement with us in respect of certain future collaborations with Genevant.

Equity Exchange and Offer to Purchase

In February 2020, we commenced (i) an offer to purchase our Common Shares from our eligible shareholders (including certain of our eligible employees and former employees) at a price per share of $37.10, (ii) an offer to surrender for cash performance options and capped value appreciation rights ("CVARs") issued in exchange for certain performance restricted stock units ("pRSUs") held by certain of our eligible employees and former employees, whereby such holder's eligible pRSUs were exchanged at a rate of approximately 0.7 performance options per eligible pRSU and, if applicable, approximately 0.7 CVARs per eligible pRSU (the "Exchange") and, immediately thereafter, 11.23% of such performance options and CVARs were surrendered to us for cash and (iii) an offer to purchase outstanding options from certain of our eligible employees and former employees, the maximum aggregate repurchase value being equal to the lesser of (a) the fair market value of approximately 11.23% of the eligible holder's outstanding vested and unvested unexercised options held as of December 27, 2019 and (b) the fair market value of 100% of the eligible holder's outstanding options that were vested and exercisable as of December 27, 2019 (subject to certain adjustments). The foregoing transactions are referred to herein as the "2020 Equity Exchange and Offer to Purchase." We additionally entered into an agreement with our Founder to repurchase a portion of his common stock held and exchange his Performance RSUs for performance options and capped value appreciation rights.

In total, in the 2020 Equity Exchange and Offer to Purchase, including participation by certain Roivant Related Parties, we purchased 25,625,933 Common Shares, exchanged 18,016,310 primarily for pRSUs for performance options and CVARs, received 631,527 surrendered performance options, received 518,893 surrendered CVARs and purchased 895,923 options in connection with the various offers to exchange and purchase, for an aggregate purchase price of approximately $1.0 billion.

2018 Equity Financing

From September through December 2018, Roivant completed an equity financing in which certain Roivant Related Parties participated:

- the Viking Global Entities (as defined herein) and certain of their affiliates purchased 155,038 Common Shares for an aggregate purchase price of $4,999,975.
- Dexxon Holdings Ltd. purchased 775,194 Common Shares for an aggregate purchase price of $25,000,006.
- SVF Investments (as defined herein) purchased 1,085,271 Common Shares for an aggregate purchase price of $34,999,989.
- the QVT Entities (as defined herein) and certain of their affiliates purchased 62,015 Common Shares for an aggregate purchase price of $1,999,983.

Certain Employment and Compensatory Arrangements

Brett Venker, currently Director, Compensation and Data, is the brother of Eric Venker, Roivant's President and Chief Operating Officer. During the fiscal year ended March 31, 2019, Brett Venker earned total cash compensation, consisting of salary and bonus, of $205,048 and was granted incentive equity awards with an aggregate grant date fair value, as computed in accordance with FASB ASC 718, of $1,025,505. During the fiscal year ended March 31, 2020, Dr. Venker earned total cash compensation, consisting of salary and bonus, of $338,273 and was granted incentive equity awards with an aggregate grant date fair value, as computed in accordance with FASB ASC 718, of $64,140. During the fiscal year ended March 31, 2021, Dr. Venker earned total cash compensation, consisting of salary and bonus, of $360,634 and was granted incentive equity awards with an aggregate grant date fair value, as computed in accordance with FASB ASC 718, of $400,039.

Other Transactions

We have granted and intend to continue to grant equity awards to our executive officers and certain of our directors. For a description of these equity awards, see the sections titled "Executive Compensation—Director Compensation" and "Executive Compensation—Post-Business Combination Director Compensation Program."

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law. See the section titled "Description of Securities—Indemnification of Directors and Officers" for additional information regarding indemnification under Bermuda law and our amended and restated bye-laws.

Related Person Transaction Policy

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of Roivant's voting securities, and any of their respective immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, is required to take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Post-Business Combination Arrangements

In connection with the Business Combination, certain agreements with certain Roivant Related Parties were entered into pursuant to the Business Combination Agreement. The agreements described in this section, or forms of such agreements as they will be in effect substantially concurrently with the completion of the business combination, are filed as exhibits to the registration statement of which this prospectus forms a part, and the following descriptions are qualified by reference thereto. These agreements include:

Transaction Support Agreement

Concurrently with the signing of the Business Combination Agreement, certain shareholders of Roivant entered into a Transaction Support Agreement (collectively, the "Transaction Support Agreements") with MAAC and Roivant, pursuant to which such shareholders of Roivant have agreed to, among other things, certain covenants and agreements, to support, or that are otherwise related to, the Business Combination, including an agreement to terminate certain existing agreements between Roivant and such shareholders, an agreement to not transfer his, her or its Roivant shares prior to the Closing and, in the case of certain Roivant shareholders also participating in the PIPE Financing, certain covenants related to the expiration or termination of the waiting period under the HSR Act, to the extent applicable, with respect to the issuance of Common Shares to such shareholder in connection with the Business Combination.

Sponsor Support Agreement

Concurrently with the execution of the Business Combination Agreement, MAAC, the MAAC Sponsor, Roivant and each of the MAAC Insiders, entered into the Sponsor Support Agreement, which was subsequently

amended on June 9, 2021 to reflect the MAAC Independent Directors and Roivant entering into respective Lock-Up Agreements and further amended on September 30, 2021.

Pursuant to the Sponsor Support Agreement, among other things: (i) the MAAC Sponsor and the MAAC Insiders reaffirmed his, her or its obligations in existing arrangements with MAAC to vote in favor of each of the proposals to be voted upon at the meeting of MAAC stockholders in connection with the Business Combination, including approval of the Business Combination Agreement and the transactions contemplated thereby; (ii) the MAAC Sponsor waived any adjustment to the conversion ratio set forth in the governing documents of MAAC or any other anti-dilution or similar protection with respect to the MAAC Class B Shares that may result from the transactions contemplated by the Business Combination; (iii) subject to, and conditioned upon, the occurrence of and effective as of, the Effective Time, the MAAC Sponsor and the MAAC Insiders agreed to terminate certain existing arrangements with MAAC, including existing registration rights and the existing lock-up obligations with respect to his, her or its MAAC Shares; (iv) the MAAC Sponsor and the MAAC Insiders that hold Common Shares immediately following the Effective Time will be granted the right to include his, her or its Common Shares in a resale registration statement to be filed in connection with the transactions contemplated by the Subscription Agreements following the Effective Time; (v) the MAAC Sponsor, Roivant and MAAC have each agreed to certain covenants related to the expiration or termination of the waiting period under the HSR Act with respect to the issuance of Common Shares to the MAAC Sponsor in connection with the Business Combination; and (vi) subject to, and conditioned upon the occurrence of, and effective as of immediately after, the Effective Time, (a) 2,033,591 shares of the Common Shares issued to the MAAC Sponsor and 10,000 shares of the Common Shares issued to each MAAC Independent Director, each in respect of its MAAC Class B Shares, will be subject to the vesting conditions described below and the other restrictions set forth in the Sponsor Support Agreement with respect to the $15 Earn-Out Shares and (b) 1,016,796 shares of the Common Shares issued to the MAAC Sponsor and 5,000 shares of the Common Shares issued to each MAAC Independent Director, each in respect of its MAAC Class B Shares, will be subject to the vesting conditions described below and the other restrictions set forth in the Sponsor Support Agreement with respect to the $20 Earn-Out Shares.

The $15 Earn-Out Shares will vest if the closing price of the Common Shares is greater than or equal to $15.00 over any twenty out of thirty trading day period during the period commencing on the earlier of (a) the date on which the registration statement of which this prospectus forms a part is declared effective or (b) November 15, 2021, and ending no later than the fifth anniversary of the Closing Date following the Closing (the “vesting period”), and the $20 Earn-Out Shares will vest if the closing price of the Common Shares is greater than or equal to $20.00 over any twenty out of thirty trading day period during the vesting period. The vesting period will, if a definitive purchase agreement with respect to a Sale (as defined in the Sponsor Support Agreement) is entered into on or prior to the end of such period, be extended to the earlier of one day after the consummation of such Sale and the termination of such definitive transaction agreement, and if a Sale occurs during such vesting period, then all of the Earn-Out Shares unvested as of such time will automatically vest immediately prior to the consummation of such Sale. If any Earn-Out Shares have not vested on or prior to the end of such vesting period, then such Earn-Out Shares will be forfeited.

PIPE Agreements

Prior to the consummation of the Business Combination, MAAC and Roivant entered into subscription agreements (collectively, the “Subscription Agreements”) with certain institutional and accredited investors, pursuant to which such investors agreed to subscribe for and purchase, and MAAC agreed to issue and sell to such investors, prior to and substantially concurrently with the closing of the Business Combination, an aggregate of 22,000,000 MAAC Class A Shares at a purchase price of $10.00 per share, for aggregate gross proceeds of $220,000,000 (the “PIPE Financing”). The PIPE Financing was consummated substantially concurrently with the closing of the Business Combination. Each MAAC Class A Share issued in the PIPE Financing was converted into one Common Share in connection with the closing of the Business Combination. The issuance of the Common Shares pursuant to the PIPE Financing was not registered the Securities Act and the Common Shares were issued in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act.

The Subscription Agreements included provisions requiring us to provide certain customary registration rights to the investors in the PIPE Financing, which we intend to satisfy with the registration statement of which this prospectus forms a part.

Registration Rights Agreement

Concurrently with the execution of the Business Combination Agreement, certain Roivant shareholders entered into the Third Amended and Restated Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, certain Roivant shareholders party thereto, subject to certain exceptions, were be granted certain customary registration rights.

Pursuant to the terms of the Registration Rights Agreement, Roivant is obligated to file a registration statement to register the resale of certain Common Shares within 30 days after the consummation of the Business Combination, which Roivant intends to satisfy with the registration statement of which this prospectus forms a part. In addition, pursuant to the terms of the Registration Rights Agreement and subject to certain requirements and customary conditions, including with regard to the number of demand rights that may be exercised and other requirements, at any time after March 30, 2022, certain significant shareholders (as provided in the Registration Rights Agreement), if any, holding at least five percent (5.0%) of the then-outstanding number of registrable securities of Roivant who is party to the Registration Rights Agreement may request that Roivant file a registration statement to register the registrable securities of Roivant held by such significant shareholder. The Registration Rights Agreement will also provide certain shareholders with "piggy-back" registration rights, subject to certain requirements and customary conditions.

Lock-Up Agreements

On May 1, 2021 and June 9, 2021, Roivant, on the one hand, and the MAAC Sponsor, both of MAAC's independent directors (the "MAAC Independent Directors") and certain Roivant equityholders, on the other hand, entered into lock-up agreements (the "Lock-Up Agreements"), pursuant to which, among other things, the MAAC Sponsor, MAAC Independent Directors and such Roivant equityholders have agreed not to, subject to, and conditioned upon the effectiveness of, the Closing, effect any sale or distribution of the Common Shares (including those underlying incentive equity awards or Warrants) held by the MAAC Sponsor, MAAC Independent Directors or such equityholders as of immediately following the Closing during the applicable lock-up period, subject to customary exceptions. The lock-up period applicable to Common Shares held by the MAAC Sponsor and MAAC Independent Directors as of immediately following the Closing will be (i) with respect to 25% of the Common Shares held by the MAAC Sponsor, six months following the Closing, (ii) with respect to an additional 25% of the Common Shares held by the MAAC Sponsor, the earlier of twelve months following the achievement of certain price-based vesting restrictions or six years from the Closing and (iii) with respect to 50% of the Common Shares held by the MAAC Sponsor, thirty-six months following the Closing. The Warrants and the Common Shares underlying Warrants held by the MAAC Sponsor as of immediately following the Closing will be subject to a corresponding lock-up period for (a) with respect to 25% of such Warrants held by the MAAC Sponsor, six months from the Closing, (b) with respect to an additional 25% of such Warrants held by the MAAC Sponsor, twelve months from Closing and (c) with respect to 50% of such warrants held by the MAAC Sponsor, thirty-six months from the Closing. The lock-up period applicable to Common Shares (including those underlying incentive equity awards) held by certain Roivant equityholders as of immediately following the Closing will be (x) with respect to 25% of the Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, six months following the Closing, (y) with respect to an additional 25% of the Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, twelve months following the Closing and (z) with respect to 50% of the Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, thirty-six months following the Closing.

PRINCIPAL SECURITYHOLDERS

The following table sets forth information regarding the beneficial ownership of the Common Shares as of December 1, 2021 by:

- each person known by the Company to be the beneficial owner of more than 5% of outstanding Common Shares;
- each of the Company's named executive officers and directors; and
- all executive officers and directors of the Company as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she, or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days. The ownership percentages set forth in the table below are based on 692,012,183 Common Shares issued and outstanding as of December 1, 2021 and unless otherwise noted below, do not take into account the issuance of any Common Shares issuable upon exercise of Warrants. However, shares that a person has the right to acquire within 60 days of December 1, 2021 are deemed issued and outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed issued and outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, we believe the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned Common Shares.

Unless otherwise indicated, the Company believes that each person named in the table below has sole voting and investment power with respect to all shares of common stock beneficially owned by such person. Except as otherwise noted below, the address for persons or entities listed in the table is c/o Roivant Sciences Ltd., Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, United Kingdom.

Name and Address of Beneficial Owners	Number of Common Shares	% of Ownership
Directors and current named executive officers:		
Matthew Gline *Chief Executive Officer and Director*	2,700,786	*
Eric Venker *President and Chief Operating Officer*	1,314,907	*
Benjamin Zimmer *Former President, Roivant Health*	1,721,991	*
James C. Momtazee *Director*	—	—
Vivek Ramaswamy *Director*	73,786,861	10.4%
Andrew Lo *Director*	690,583	*
Patrick Machado *Director*	468,895	*
Keith Manchester *Director*	—	—
Ilan Oren *Director*	—	—
Daniel Gold *Director*	—	—
Masayo Tada *Director*	—	—

Name and Address of Beneficial Owners	Number of Common Shares	% of Ownership
All directors and executive officers as a group (14 persons)	88,438,492	12.3%
Five Percent Holders (excluding directors):		
SVF Investments(1)	99,375,586	14.4%
QVT Entities(2)	129,393,817	18.7%
Dexxon Holdings(3)	98,809,158	14.3%
Viking Global Entities(4)	88,238,700	12.8%
Sumitomo Dainippon Pharma Co., Ltd.(5).	86,367,360	12.5%

* Less than 1%

(1) Securities held of record by SVF Investments (UK) Limited ("SVF Investments"). SVF GP (Jersey) Limited is the general partner of Softbank Vision Fund LP, which is the managing member of SVF Holdings (UK) LLP ("SVF Holdings"), which is the sole owner of SVF Investments. SB Investment Advisers (UK) Limited ("SBIA UK") has been appointed by SVF GP (Jersey) Limited as the alternative investment fund manager ("AIFM") of SoftBank Vision Fund LP. SBIA UK is authorized and regulated by the UK Financial Conduct Authority and is exclusively responsible for making all decisions related to the acquisition, structuring, financing and disposal of SoftBank Vision Fund LP's investments. Voting and investment determinations with respect to the securities held of record by SVF Investments are made by the board of directors of SBIA UK, which consists of Rajeev Misra, Saleh Romeih, Kalika Jayasekera and Neil Hadley. Accordingly, each of the foregoing entities and individuals may be deemed to share beneficial ownership of the securities held of record by SVF Investments. Each of them disclaims any such beneficial ownership. The registered address for Softbank Vision Fund LP and SVF GP (Jersey) Limited is Aztec Group House 11-15 Seaton Place, St. Helier, Y9 JE40QH. The principal address of SVF Investments, SVF Holdings, and SBIA UK is 69 Grosvenor Street, London, United Kingdom W1K 3JP.

(2) Consists of Common Shares held by QVT Financial Investment Cayman Ltd., QVT Roiv Hldgs Offshore Ltd., QVT Roiv Hldgs Onshore Ltd., QVT Deferred Compensation Holdings Ltd., QVT P&E Roiv Hldgs Ltd. and Fourth Avenue Capital Partners LP (together, the "QVT Entities"). Fourth Avenue Capital Partners GP LLC may be deemed to share beneficial ownership of the Common Shares held by Fourth Avenue Capital Partners LP. Each of QVT Financial LP and QVT Financial GP LLC may be deemed to share beneficial ownership of the Common Shares held by the QVT Entities. The Managing Members of QVT Financial GP LLC and Fourth Avenue Capital Partners GP LLC are Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu, each of whom disclaims beneficial ownership of the securities held by the QVT Entities except to the extent of any pecuniary interest. The principal business address for the QVT Entities, QVT Financial LP, QVT Financial GP LLC, Fourth Avenue Capital Partners GP LLC and the Managing Members is 888 Seventh Avenue, 27th Floor, New York, NY 10106.

(3) Consists of Common Shares held by Dexxon Holdings Ltd. ("Dexxon Holdings") and Dexcel Pharma Technologies Ltd. ("Dexcel Pharma"). Dan Oren is the sole shareholder and sole director of Dexxon Holdings and the ultimate (indirect) sole shareholder and the Executive Chairman of Dexcel Pharma. As such, each of Dexxon Holdings, Dexcel Pharma and Dan Oren may be deemed to share beneficial ownership of the Common Shares. The principal business address of Dexxon Holdings and Dan Oren is 1 Dexcel Street, Or Akiva, 3060000, Israel. The principal business address of Dexcel Pharma is 21 Nahum Haftzadi Street, Jerusalem, 9548402, Israel.

(4) Consists of Common Shares held by Viking Global Equities Master Ltd. ("VGEM"), Viking Global Equities II LP ("VGEII"), Viking Long Fund Master Ltd. ("VLFM") and Viking Global Opportunities Illiquid Investments Sub-Master LP ("Opportunities Fund," and together with all of the preceding entities, the "Viking Global Entities") and includes 1,000,000 Common Shares issued to the Viking Global Entities in connection with the PIPE Financing. VGEM has the power to dispose of and vote the shares directly owned by it, which power may be exercised by its investment manager, Viking Global Performance LLC ("VGP"), and by Viking Global Investors LP ("VGI"), which provides managerial services to VGEM. VGEII has the authority to dispose of and vote the shares directly owned by it, which power may be

exercised by its general partner, VGP, and by VGI, which provides managerial services to VGEII. VLFM has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its investment manager, Viking Long Fund GP LLC ("VLFGP"), and by VGI, which provides managerial services to VLFM. Opportunities Fund has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC ("Opportunities GP"), and by VGI, which provides managerial services to Opportunities Fund. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI), VGP, VLFGP and Viking Global Opportunities GP LLC (the sole member of Opportunities GP) have shared authority to direct the voting and disposition of investments beneficially owned by VGI, VGP, VLFGP and Opportunities GP. The business address of each of the Viking Global Entities is 55 Railroad Avenue, Greenwich, Connecticut 06830.

(5) Consists of Common Shares held by Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo"), including 7,500,000 Common Shares issued to Sumitomo in connection with the PIPE Financing. The principal business address of Sumitomo is 6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045 Japan.

SELLING HOLDERS

This prospectus relates to the possible offer and resale by the Holders of up to 17,407,773 Common Shares. All of the data in the following tables is as of December 10, 2021.

The following tables are prepared based on information provided to us by the Holders. They set forth the name and address of the Holders, the aggregate number of Common Shares that the Holders may offer pursuant to this prospectus, and the beneficial ownership of the Holders both before and after the offering. We have based percentage ownership prior to this offering on 692,012,183 Common Shares outstanding as of December 10, 2021. The following tables do not reflect the beneficial ownership of any Common Shares Stock issuable upon exercise of Warrants or incentive equity awards unless such securities are exercisable or convertible within 60 days.

We cannot advise you as to whether the Holders will in fact sell any or all of the securities set forth in the tables below. In addition, subject to the lock-up provisions described in "Securities Act Restrictions on Resale of Securities—Lock-up Provisions," which are applicable to certain of the shares registered hereby, the Holders may sell, transfer or otherwise dispose of, at any time and from time to time, such securities in transactions exempt from the registration requirements of the Securities Act after the date of this prospectus. For purposes of the below tables, unless otherwise indicated below, we have assumed that the Holders will have sold all of the securities covered by this prospectus upon the completion of the offering.

Unless otherwise indicated below, the address of each beneficial owner listed in the tables below is c/o Roivant Sciences Ltd., Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, United Kingdom.

Name and Address of Holders	Beneficial Ownership Before the Offering		Shares to be Registered Hereby	Beneficial Ownership After Offering	
	Number of Shares	%	Number of Shares	Number of Shares	%
Parkway Limited(1)	595,400	*	197,036	—	—
Chengwei Capital HK Limited(2)	11,575,980	1.7%	11,575,980	—	—
Sequoia Capital China(3)	4,953,984	*	4,953,984	—	—
Junson Development International Limited(4)	2,057,155	*	680,773	1,376,382	*

* Less than 1%.

(1) Xie Yi Jing is a director of Parkway Limited and has voting and dispositive power over the Common Shares. The address of each of Mr. Jing and Parkway Limited is 25F East Tower, Raffles City, the Bund, No. 1089 East Daming Road, Shanghai, China. 398,364 Common Shares held by Parkway Limited were acquired prior to the closing of the Business Combination and are therefore subject to a six month lock-up, measured from the closing of the Business Combination, while 197,036 Common Shares held by Parkway Limited were acquired following the closing of the Business Combination and are therefore not subject to any lock-up provision. The "Beneficial Ownership After Offering" column assumes that Parkway Limited will have also sold all of the securities that Parkway Limited has separately registered pursuant to our registration statement on form S-1 (File No. 333-260619).

(2) Chengwei Capital HK Limited is wholly owned by Chengwei Evergreen Capital, LP. Chengwei Evergreen Management, LLC is the general partner and wholly controls Chengwei Evergreen Capital, LP. Chengwei Evergreen Management, LLC in return is controlled by EXL Holdings, LLC, which is controlled by Eric X. Li. Eric X. Li is a Director of Chengwei Capital HK Limited and has voting and dispositive power over the Common Shares. The address of each of Eric X. Li and Chengwei Capital HK Limited is Room 3303A The Centrium, 60 Wyndham Street Central, Hong Kong. 7,745,151 Common Shares held by Chengwei Capital HK Limited were acquired prior to the closing of the Business Combination and are therefore subject to a six month lock-up, measured from the closing of the Business Combination, while 3,830,829 Common Shares held by Chengwei Capital HK Limited were acquired following the closing of the Business Combination and are therefore not subject to any lock-up provision.

(3) Represents 4,953,984 Common Shares held by SCC Venture VII Holdco H, Ltd., of which, 3,314,565 Common Shares held by SCC Venture VII Holdco H, Ltd. were acquired prior to the closing of the Business Combination and are therefore subject to a six month lock-up, measured from the closing of the Business Combination, while 1,639,419 Common Shares held by SCC Venture VII Holdco H, Ltd. were acquired following the closing of the Business Combination and are therefore not subject to any lock-up provision. SCC Venture VII Holdco H, Ltd. is an exempted company with limited liability incorporated under the law of the Cayman Islands, and is wholly owned by Sequoia Capital China Venture Fund VII, L.P. The general partner of Sequoia Capital China Venture Fund VII, L.P. is SC China Venture VII Management, L.P., whose general partner is SC China Holding Limited. SC China Holding Limited is wholly owned by SNP China Enterprises Limited, which in turn is wholly owned by Mr. Neil Nanpeng Shen. The registered address of SCC Venture VII Holdco H, Ltd. is Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(4) Mr. Kui CAI is a director of Junson Development International Limited and has voting and dispositive power over the Common Shares. The address of each of Mr. Kui CAI and Junson Development International Limited is Units 5211-12, 52/F, The Center, 99 Queen’s Road Central, Hong Kong. 1,376,382 Common Shares held by Junson Development International Limited were acquired prior to the closing of the Business Combination and are therefore subject to a six month lock-up, measured from the closing of the Business Combination, while 680,773 Common Shares held by Junson Development International Limited were acquired following the closing of the Business Combination and are therefore not subject to any lock-up provision.

DESCRIPTION OF SECURITIES

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities, and is qualified by reference to our Charter, our Bylaws and the warrant-related documents described herein, which are exhibits to the registration statement of which this prospectus is a part. We urge to you read each of the Charter, the Bylaws and the warrant-related documents described herein in their entirety for a complete description of the rights and preferences of our securities.

General

We are an exempted company incorporated under the laws of Bermuda. We are registered with the Registrar of Companies in Bermuda under registration number 48931. We were incorporated on 7 April 2014 under the name Valor Biotechnology Ltd. We changed our name to Roivant Sciences Ltd. on 5 November 2014. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

The objects of our business are unrestricted, and Roivant Sciences Ltd. has the capacity of a natural person. We can therefore undertake activities without restriction on our capacity. Prior to the consummation of the Business Combination, our shareholders will approve certain amendments to our bye-laws that will become effective upon the closing of this offering. The following description assumes that such amendments have become effective.

There have been no public takeover offers by third parties for our shares nor any public takeover offers by us for the shares of another company that have occurred during the last or current financial years.

Share Capital

Immediately following the closing of the Business Combination and after giving effect to the subdivision of Common Shares, our authorized share capital will consist of 7,000,000,000 Common Shares, $0.000000341740141 par value per common share. As of December 1, 2021, we had 692,012,183 Common Shares issued and outstanding. All of the issued Common Shares prior to the closing of this offering are fully paid. Pursuant to our amended and restated bye-laws, subject to the requirements of Nasdaq, and to any resolution of the shareholders to the contrary, our board of directors is authorized to issue any of our authorized but unissued shares. There are no limitations on the right of non-Bermudians or non-residents of Bermuda to hold or vote our shares provided Common Shares remain listed on an appointed stock exchange, which includes Nasdaq.

Common Shares

Holders of Common Shares have no pre-emptive, redemption, conversion or sinking fund rights. Holders of Common Shares are entitled to one vote per share on all matters submitted to a vote of holders of Common Shares. Unless a different majority is required by law or by our amended and restated bye-laws, resolutions to be approved by holders of Common Shares require approval by a simple majority of votes cast at a meeting at which a quorum is present.

In the event of our liquidation, dissolution or winding up, the holders of Common Shares are entitled to share equally and ratably in our assets, if any, remaining after the payment of all of our debts and liabilities, subject to any liquidation preference on any issued and outstanding preference shares.

Preference Shares

Pursuant to Bermuda law and our amended and restated bye-laws, our board of directors may, by resolution, establish one or more series of preference shares having such number of shares, designations, dividend rates,

relative voting rights, conversion or exchange rights, redemption rights, liquidation rights, rights to elect or appoint directors and other relative participation, optional or other special rights, qualifications, limitations or restrictions as may be fixed by the board of directors without any further shareholder approval. Such rights, preferences, powers and limitations, as may be established, could have the effect of discouraging an attempt to obtain control of our company.

Dividend Rights

Under Bermuda law, a company may not declare or pay dividends if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due; or (2) that the realizable value of its assets would thereby be less than its liabilities. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares. We do not anticipate paying cash dividends in the foreseeable future.

Variation of Rights

If at any time we have more than one class of shares, the rights attaching to any class, unless otherwise provided for by the terms of issue of the relevant class, may be varied either: (1) with the consent in writing of the holders of 66 2/3% of the issued shares of that class; or (2) with the sanction of a resolution passed by a majority of the votes cast at a general meeting of the relevant class of shareholders at which a quorum consisting of at least one person holding or representing a majority of the issued shares of the relevant class is present. Our amended and restated bye-laws specify that the creation or issue of shares ranking equally with existing shares will not, unless expressly provided by the terms of issue of existing shares, vary the rights attached to existing shares. In addition, the creation or issue of preference shares ranking prior to Common Shares will not be deemed to vary the rights attached to Common Shares or, subject to the terms of any other class or series of preference shares, to vary the rights attached to any other class or series of preference shares.

Transfer of Shares

Our board of directors may, in its absolute discretion and without assigning any reason, refuse to register the transfer of a share on the basis that it is not fully paid. Our board of directors may also refuse to recognize an instrument of transfer of a share unless it is accompanied by the relevant share certificate and such other evidence of the transferor's right to make the transfer as our board of directors shall reasonably require or unless all applicable consents, authorizations and permissions of any governmental agency or body in Bermuda have been obtained. Subject to these restrictions, a holder of Common Shares may transfer the title to all or any of his or her Common Shares by completing an instrument of transfer in writing in such form as our board of directors may accept. The instrument of transfer must be signed by the transferor and transferee, although in the case of a fully paid share our board of directors may accept the instrument signed only by the transferor.

Meetings of Shareholders

Under Bermuda law, a company is required to convene at least one general meeting of shareholders each calendar year, which we refer to as the annual general meeting. While Bermuda law permits the shareholders to waive the requirement to hold an annual general meeting by resolution (either for a specific year or a period of time or indefinitely), our amended and restated bye-laws provide that, notwithstanding, an annual general meeting shall be held in each year.

Bermuda law provides that a special general meeting of shareholders may be called by the board of directors of a company and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings. Bermuda law also requires that shareholders be given at least five days' advance notice of a general meeting, but the accidental omission to give

notice to any person does not invalidate the proceedings at a meeting. Our amended and restated bye-laws provide that our principal executive officer or the chairperson of our board of directors or any two directors or any director and the secretary or our board of directors may convene an annual general meeting and our principal executive officer or the chairperson of our board of directors or our board of directors may convene a special general meeting. Under our amended and restated bye-laws, at least 14 days' notice of an annual general meeting or 10 days' notice of a special general meeting must be given to each shareholder entitled to vote at such meeting. This notice requirement is subject to the ability to hold such meetings on shorter notice if such notice is agreed: (1) in the case of an annual general meeting by all of the shareholders entitled to attend and vote at such meeting; or (2) in the case of a special general meeting by a majority in number of the shareholders entitled to attend and vote at the meeting holding not less than 95% in nominal value of the shares entitled to vote at such meeting. The quorum required for a general meeting of shareholders is two or more persons present in person at the start of the meeting and representing in person or by proxy in excess of 50% of all issued and outstanding Common Shares.

Access to Books and Records and Dissemination of Information

Members of the general public have a right to inspect the public documents of a company available at the office of the Registrar of Companies in Bermuda. These documents include a company's memorandum of association, including its objects and powers, and certain alterations to the memorandum of association. The shareholders have the additional right to inspect the bye-laws of the company, minutes of general meetings and the company's audited financial statements, which must be presented in the annual general meeting. The register of members of a company is also open to inspection by shareholders and by members of the general public without charge. The register of members is required to be open for inspection for not less than two hours in any business day (subject to the ability of a company to close the register of members for not more than thirty days in a year). A company is required to maintain its share register in Bermuda but may, subject to the provisions of the Companies Act establish a branch register outside of Bermuda. A company is required to keep at its registered office a register of directors and officers that is open for inspection for not less than two hours in any business day by members of the public without charge. Bermuda law does not, however, provide a general right for shareholders to inspect or obtain copies of any other corporate records.

Election and Removal of Directors

Our amended and restated bye-laws provide that our board of directors shall consist of not less than five (5) Directors and not more than such maximum number of Directors as the Board may from time to time determine, being initially fifteen (15) Directors. Upon the closing of this offering, our board of directors will consist of six directors. Our board of directors will be divided into three classes that are, as nearly as possible, of equal size. Each class of directors will be elected for a three-year term of office, but the terms will be staggered so that the term of only one class of directors expires at each annual general meeting. The initial terms of the Class I, Class II and Class III directors will expire in 2022, 2023 and 2024, respectively. At each succeeding annual general meeting, successors to the class of directors whose term expires at the annual general meeting will be elected for a three-year term.

A shareholder holding any percentage of the Common Shares in issue may propose for election as a director someone who is not an existing director or is not proposed by our board of directors. Where a director is to be elected at an annual general meeting, notice of any such proposal for election must be given not less than 90 days nor more than 120 days before the anniversary of the last annual general meeting prior to the giving of the notice or, in the event the annual general meeting is called for a date that is not less than 30 days before or after such anniversary the notice must be given not later than 10 days following the earlier of the date on which notice of the annual general meeting was posted to shareholders or the date on which public disclosure of the date of the annual general meeting was made. Where a director is to be elected at a special general meeting; provided, that our board of directors has determined that shareholders may nominate persons for election at such special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of

the special general meeting was posted to shareholders or the date on which public disclosure of the date of the special general meeting was made.

A director may be removed, only with cause, by the shareholders by the affirmative vote of at least 66$^{2/3}$% of the issued and outstanding voting shares entitled to vote for the election of directors, provided notice of the shareholders meeting convened to remove the director is given to the director. The notice must contain a statement of the intention to remove the director and a summary of the facts justifying the removal and must be served on the director not less than 14 days before the meeting. The director is entitled to attend the meeting and be heard on the motion for his or her removal.

Proceedings of Board of Directors

Our amended and restated bye-laws provide that our business is to be managed and conducted by our board of directors. Bermuda law permits individual and corporate directors and there is no requirement in our bye-laws or Bermuda law that directors hold any of our shares. There is also no requirement in our amended and restated bye-laws or Bermuda law that our directors must retire at a certain age.

The compensation of our directors will be determined by the board of directors, and there is no requirement that a specified number or percentage of “independent” directors must approve any such determination. Our directors may also be paid all travel, hotel and other reasonable out-of-pocket expenses properly incurred by them in connection with our business or their duties as directors.

A director who discloses a direct or indirect interest in any contract or arrangement with us as required by Bermuda law may be entitled to be counted in the quorum for such meeting and to vote in respect of any such contract or arrangement in which he or she is interested unless the chairman of the relevant meeting of the board of directors determines that such director is disqualified from voting.

Indemnification of Directors and Officers

Section 98 of the Companies Act provides generally that a Bermuda company may indemnify its directors, officers and auditors against any liability which by virtue of any rule of law would otherwise be imposed on them in respect of any negligence, default, breach of duty or breach of trust, except in cases where such liability arises from fraud or dishonesty of which such director, officer or auditor may be guilty in relation to the company. Section 98 further provides that a Bermuda company may indemnify its directors, officers and auditors against any liability incurred by them in defending any proceedings, whether civil or criminal, in which judgment is awarded in their favor or in which they are acquitted or granted relief by the Supreme Court of Bermuda pursuant to Section 281 of the Companies Act.

Our amended and restated bye-laws provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty, and that we shall advance funds to our officers and directors for expenses incurred in their defense upon receipt of an undertaking to repay the funds if any allegation of fraud or dishonesty is proved. Our amended and restated bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company’s directors or officers for any act or failure to act in the performance of such director’s or officer’s duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors’ and officers’ liability policy for such purpose.

Amendment of Memorandum of Association and Bye-laws

Bermuda law provides that the memorandum of association of a company may be amended by a resolution passed at a general meeting of shareholders. Our amended and restated bye-laws provide that no bye-law shall be

rescinded, altered or amended, and no new bye-law shall be made, unless it shall have been approved by a resolution of our board of directors and by a resolution of our shareholders holding at least 66$^{2/3}$% of all votes cast on the resolution. The memorandum or association shall not be rescinded, altered or amended without a resolution of our board of directors and a resolution of our shareholders holding at least 66$^{2/3}$% of all votes cast on the resolution.

Under Bermuda law, the holders of an aggregate of not less than 20% in par value of a company's issued share capital or any class thereof have the right to apply to the Supreme Court of Bermuda for an annulment of any amendment of the memorandum of association adopted by shareholders at any general meeting, other than an amendment that alters or reduces a company's share capital as provided in the Companies Act. Where such an application is made, the amendment becomes effective only to the extent that it is confirmed by the Supreme Court of Bermuda. An application for an annulment of an amendment of the memorandum of association must be made within 21 days after the date on which the resolution altering the company's memorandum of association is passed and may be made on behalf of persons entitled to make the application by one or more of their number as they may appoint in writing for the purpose. No application may be made by shareholders voting in favor of the amendment.

Amalgamations and Mergers

The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its shareholders. Unless the company's bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company. Our amended and restated bye-laws provide that the approval of a 66$^{2/3}$% of shareholders voting at a meeting to approve the amalgamation or merger agreement shall be sufficient (other than in respect of an amalgamation or merger constituting a "business combination"), and the quorum for such meeting shall be two or more Persons present in person and representing in person or by proxy in excess of 50% of the total voting rights of all issued and outstanding shares of the Company.

Under Bermuda law, in the event of an amalgamation or merger of a Bermuda company with another company or corporation, a shareholder of the Bermuda company who did not vote in favor of the amalgamation or merger and who is not satisfied that fair value has been offered for such shareholder's shares may, within one month of notice of the shareholders meeting, apply to the Supreme Court of Bermuda to appraise the fair value of those shares.

Business Combinations

Although the Companies Act does not contain specific provisions regarding "business combinations" between companies organized under the laws of Bermuda and "interested shareholders," we have included these provisions in our bye-laws. Specifically, our bye-laws contain provisions which prohibit us from engaging in a business combination with an interested shareholder for a period of three years after the date of the transaction in which the person became an interested shareholder, unless, in addition to any other approval that may be required by applicable law:

- prior to the date of the transaction that resulted in the shareholder becoming an interested shareholder, our board of directors approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of our issued and voting shares outstanding at the time the transaction commenced; or

- after the date of the transaction that resulted in the shareholder becoming an interested shareholder, the business combination is approved by our board of directors and authorized at an annual or special meeting of shareholders by the affirmative vote of at least 66$^{2/3}$% of our issued and outstanding voting shares that are not owned by the interested shareholder.

For purposes of these provisions, a "business combination" includes recapitalizations, mergers, amalgamations, consolidations, exchanges, asset sales, leases, certain issues or transfers of shares or other securities and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is any person or entity that beneficially owns 15% or more of our issued and outstanding voting shares and any person or entity affiliated with or controlling or controlled by that person or entity.

Shareholder Suits

Class actions and derivative actions are generally not available to shareholders under Bermuda law. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than that which actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some part of the shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company.

Our amended and restated bye-laws contain a provision by virtue of which our shareholders waive any claim or right of action that they have, both individually and on our behalf, against any director or officer in relation to any action or failure to take action by such director or officer, except in respect of any fraud or dishonesty of such director or officer. We have been advised by the SEC that in the opinion of the SEC, the operation of this provision as a waiver of the right to sue for violations of federal securities laws would likely be unenforceable in U.S. courts.

Capitalization of Profits and Reserves

Pursuant to our amended and restated bye-laws, our board of directors may (1) capitalize any part of the amount of our share premium or other reserve accounts or any amount credited to our profit and loss account or otherwise available for distribution by applying such sum in paying up unissued shares to be allotted as fully paid bonus shares pro rata (except in connection with the conversion of shares) to the shareholders; or (2) capitalize any sum standing to the credit of a reserve account or sums otherwise available for dividend or distribution by paying up in full, partly paid or nil paid shares of those shareholders who would have been entitled to such sums if they were distributed by way of dividend or distribution.

Untraced Shareholders

Our amended and restated bye-laws provide that our board of directors may forfeit any dividend or other monies payable in respect of any shares that remain unclaimed for six years from the date when such monies became due for payment. In addition, we are entitled to cease sending dividend warrants and checks by post or otherwise to a shareholder if such instruments have been returned undelivered to, or left uncashed by, such shareholder on at least two consecutive occasions or, following one such occasion, reasonable enquires have failed to establish the shareholder's new address. This entitlement ceases if the shareholder claims a dividend or cashes a dividend check or a warrant.

Warrants

Public Warrants

Each whole Warrant entitles the registered holder to purchase one Common Share at a price of $11.50 per share, subject to adjustment as discussed below, at any time commencing October 30, 2021, provided in each case that Roivant has an effective registration statement under the Securities Act covering the Common Shares issuable upon exercise of the Warrants and a current prospectus relating to them is available (or Roivant permits holders to exercise their Warrants on a cashless basis under the circumstances specified in the warrant agreement) and such shares are registered, qualified or exempt from registration under the securities, or blue sky, laws of the state of residence of the holder. Pursuant to the warrant agreement, a holder of Warrants may exercise its Warrants only for a whole number of Common Shares. This means only a whole Warrant may be exercised at a given time by a Warrant holder. No fractional Warrants will be issued upon separation of the units and only whole Warrants will trade. Accordingly, unless you purchase at least two units, you will not be able to receive or trade a whole warrant. The Warrants will expire at 5:00 p.m., New York City time on September 30, 2026.

Roivant will not be obligated to deliver any Common Shares pursuant to the exercise of a Warrant and will have no obligation to settle such Warrant exercise unless a registration statement under the Securities Act with respect to the Common Shares underlying the Warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration, or a valid exemption from registration is available. No Warrant will be exercisable and Roivant will not be obligated to issue a Common Share upon exercise of a Warrant unless the Common Shares issuable upon such Warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the Warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such Warrant will not be entitled to exercise such Warrant and such Warrant may have no value and expire worthless. In no event will Roivant be required to net cash settle any warrant. In the event that a registration statement is not effective for the exercised Warrants, the purchaser of a unit containing such Warrant will have paid the full purchase price for the unit solely for the share of Common Shares underlying such unit.

As soon as practicable, but in no event later than twenty business days after the Closing, Roivant will use its commercially reasonable efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the Common Shares issuable upon exercise of the Warrants. Roivant will use its commercially reasonable efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration or redemption of the Warrants in accordance with the provisions of the warrant agreement. If a registration statement covering the issuance of the Common Shares issuable upon exercise of the Warrants is not effective by the 60th business day after the Closing, Warrant holders may, until such time as there is an effective registration statement and during any period when Roivant will have failed to maintain an effective registration statement, exercise Warrants on a “cashless basis” in accordance with Section 3(a)(9) of the Securities Act or another exemption. In addition, if Common Shares are at the time of any exercise of a Warrant not listed on a national securities exchange such that they satisfy the definition of a “covered security” under Section 18(b)(1) of the Securities Act, Roivant may, at its option, require holders of its public Warrants who exercise their Warrants to do so on a “cashless basis” in accordance with Section 3(a)(9) of the Securities Act and, in the event Roivant elects to do so, Roivant will not be required to file or maintain in effect a registration statement, but Roivant will use its best efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. In such event, each holder would pay the exercise price by surrendering each such Warrant for that number of Common Shares equal to the lesser of (A) the quotient obtained by dividing (x) the product of the number of Common Shares underlying the Warrants, multiplied the excess of the “fair market value” less the exercise price of the Warrants by (y) the fair market value and (B) 0.361. The “fair market value” shall mean the volume weighted average price of Common Shares for the 10 trading days ending on the trading day prior to the date on which the notice of exercise is received by the warrant agent.

Redemption of Warrants When the Price per Common Share Equals or Exceeds $18.00

Once the Warrants become exercisable, Roivant may redeem the outstanding Warrants (except as described herein with respect to the private placement Warrants):

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption to each Warrant holder; and
- if, and only if, the last reported sale price of the Common Shares for any 20 trading days within a 30-trading day period ending three business days before Roivant sends to the notice of redemption to the Warrant holders (which Roivant refers to as the "Reference Value") equals or exceeds $18.00 per share (as adjusted for share subdivisions, share capitalizations, dividends, reorganizations, recapitalizations and the like).

If and when the Warrants become redeemable by us, Roivant may exercise its redemption right even if Roivant is unable to register or qualify the underlying securities for sale under all applicable state securities laws. However, Roivant will not redeem the Warrants unless an effective registration statement under the Securities Act covering the Common Shares issuable upon exercise of the Warrants is effective and a current prospectus relating to those Common Shares is available throughout the 30-day redemption period.

Roivant established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the Warrant exercise price. If the foregoing conditions are satisfied and Roivant issues a notice of redemption of the Warrants, each Warrant holder will be entitled to exercise his, her or its Warrant prior to the scheduled redemption date. Any such exercise would not be done on a "cashless" basis and would require the exercising Warrant holder to pay the exercise price for each Warrant being exercised. However, the price of the Common Shares may fall below the $18.00 redemption trigger price (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like) as well as the $11.50 (for whole shares) Warrant exercise price after the redemption notice is issued.

Redemption of Warrants When the Price per Common Share Equals or Exceeds $10.00

Once the Warrants become exercisable, Roivant may redeem the outstanding Warrants:

- in whole and not in part;
- at $0.10 per Warrant upon a minimum of 30 days' prior written notice of redemption; provided that holders will be able to exercise their Warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to the table below, based on the redemption date and the "fair market value" of Common Shares (as defined below);
- if, and only if, the Reference Value (as defined above under—"Redemption of Warrants When the Price per Common Share Equals or Exceeds $18.00") equals or exceeds $10.00 per share (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like); and
- if the Reference Value is less than $18.00 per share (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like) the private placement Warrants must also be concurrently called for redemption on the same terms (except as described above with respect to a holder's ability to cashless exercise its Warrants) as the outstanding public Warrants, as described above.

The numbers in the table below represent the number of Common Shares that a Warrant holder will receive upon exercise in connection with a redemption by Roivant pursuant to this redemption feature, based on the "fair market value" of Common Shares on the corresponding redemption date (assuming holders elect to exercise their
Warrants and such Warrants are not redeemed for $0.10 per warrant), determined based on volume-weighted average price of Common Shares as reported during the 10 trading days immediately following the date on which

the notice of redemption is sent to the holders of Warrants, and the number of months that the corresponding redemption date precedes the expiration date of the Warrants, each as set forth in the table below. Roivant provides its Warrant holders with the final fair market value no later than one business day after the 10-trading day period described above ends.

Pursuant to the warrant agreement, references above to Common Shares shall include a security other than Common Shares into which the Common Shares have been converted or exchanged for in the event Roivant is not the surviving company in an initial business combination. The numbers in the table below will not be adjusted when determining the number of Common Shares to be issued upon exercise of the Warrants if Roivant is not the surviving entity following an initial business combination.

The share prices set forth in the column headings of the table below will be adjusted as of any date on which the number of shares issuable upon exercise of a Warrant is adjusted as set forth under the heading "*—Anti-dilution Adjustments*" below. The adjusted share prices in the column headings will equal the share prices immediately prior to such adjustment, multiplied by a fraction, the numerator of which is the number of shares deliverable upon exercise of a Warrant immediately prior to such adjustment and the denominator of which is the number of shares deliverable upon exercise of a Warrant as so adjusted. The number of shares in the table below shall be adjusted in the same manner and at the same time as the number of shares issuable upon exercise of a warrant.

	Fair Market Value of Common Shares								
Redemption Date (period to expiration of Warrants)	[2]**$10.00**	**$11.00**	**$12.00**	**$13.00**	**$14.00**	**$15.00**	**$16.00**	**$17.00**	[3]**$18.00**
60 months	0.261	0.281	0.297	0.311	0.324	0.337	0.348	0.358	0.361
57 months	0.257	0.277	0.294	0.310	0.324	0.337	0.348	0.358	0.361
54 months	0.252	0.272	0.291	0.307	0.322	0.335	0.347	0.357	0.361
51 months	0.246	0.268	0.287	0.304	0.320	0.333	0.346	0.357	0.361
48 months	0.241	0.263	0.283	0.301	0.317	0.332	0.344	0.356	0.361
45 months	0.235	0.258	0.279	0.298	0.315	0.330	0.343	0.356	0.361
42 months	0.228	0.252	0.274	0.294	0.312	0.328	0.342	0.355	0.361
39 months	0.221	0.246	0.269	0.290	0.309	0.325	0.340	0.354	0.361
36 months	0.213	0.239	0.263	0.285	0.305	0.323	0.339	0.353	0.361
33 months	0.205	0.232	0.257	0.280	0.301	0.320	0.337	0.352	0.361
30 months	0.196	0.224	0.250	0.274	0.297	0.316	0.335	0.351	0.361
27 months	0.185	0.214	0.242	0.268	0.291	0.313	0.332	0.350	0.361
24 months	0.173	0.204	0.233	0.260	0.285	0.308	0.329	0.348	0.361
21 months	0.161	0.193	0.223	0.252	0.279	0.304	0.326	0.347	0.361
18 months	0.146	0.179	0.211	0.242	0.271	0.298	0.322	0.345	0.361
15 months	0.130	0.164	0.197	0.230	0.262	0.291	0.317	0.342	0.361
12 months	0.111	0.146	0.181	0.216	0.250	0.282	0.312	0.339	0.361
9 months	0.090	0.125	0.162	0.199	0.237	0.272	0.305	0.336	0.361
6 months	0.065	0.099	0.137	0.178	0.219	0.259	0.296	0.331	0.361
3 months	0.034	0.065	0.104	0.150	0.197	0.243	0.286	0.326	0.361
0 months	—	—	0.042	0.115	0.179	0.233	0.281	0.323	0.361

The exact fair market value and redemption date may not be set forth in the table above, in which case, if the fair market value is between two values in the table or the redemption date is between two redemption dates in the table, the number of Common Shares to be issued for each Warrant exercised will be determined by a straight-line interpolation between the number of shares set forth for the higher and lower fair market values and the earlier and later redemption dates, as applicable, based on a 365 or 366-day year, as applicable. For example, if the volume-weighted average price of Common Shares as reported during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of the Warrants is $11.00 per share,

and at such time there are 57 months until the expiration of the Warrants, holders may choose to, in connection with this redemption feature, exercise their Warrants for 0.277 Common Shares for each whole warrant. For an example where the exact fair market value and redemption date are not as set forth in the table above, if the volume-weighted average price of Common Shares as reported during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of the Warrants is $13.50 per share, and at such time there are 38 months until the expiration of the Warrants, holders may choose to, in connection with this redemption feature, exercise their Warrants for 0.298 Common Shares for each whole warrant. In no event will the Warrants be exercisable in connection with this redemption feature for more than 0.361 Common Shares per Warrant (subject to adjustment).

This redemption feature differs from the typical warrant redemption features used in some other blank check offerings, which typically only provide for a redemption of Warrants for cash (other than the Private Placement Warrants) when the trading price for the Common Shares exceeds $18.00 per share for a specified period of time. This redemption feature is structured to allow for all of the outstanding Warrants to be redeemed when the Common Shares are trading at or above $10.00 per share, which may be at a time when the trading price of Common Shares is below the exercise price of the Warrants. Roivant has established this redemption feature to provide Roivant with the flexibility to redeem the Warrants without the Warrants having to reach the $18.00 per share threshold set forth above under "—Redemption of Warrants When the Price per Common Share Equals or Exceeds $18.00." Holders choosing to exercise their Warrants in connection with a redemption pursuant to this feature will, in effect, receive a number of shares for their Warrants based on an option pricing model with a fixed volatility input as of the date of this prospectus. This redemption right provides Roivant with an additional mechanism by which to redeem all of the outstanding Warrants, and therefore have certainty as to our capital structure as the Warrants would no longer be outstanding and would have been exercised or redeemed. Roivant will be required to pay the applicable redemption price to Warrant holders if Roivant chooses to exercise this redemption right and it will allow Roivant to quickly proceed with a redemption of the Warrants if Roivant determines it is in our best interest to do so. As such, Roivant would redeem the Warrants in this manner when Roivant believes it is in our best interest to update our capital structure to remove the Warrants and pay the redemption price to the Warrant holders.

As stated above, Roivant can redeem the Warrants when the Common Shares are trading at a price starting at $10.00, which is below the exercise price of $11.50, because it provides certainty with respect to our capital structure and cash position while providing Warrant holders with the opportunity to exercise their Warrants on a cashless basis for the applicable number of shares. If Roivant chooses to redeem the Warrants when the Common Shares are trading at a price below the exercise price of the Warrants, this could result in the Warrant holders receiving fewer Common Shares than they would have received if they had chosen to wait to exercise their Warrants for Common Shares if and when such Common Shares were trading at a price higher than the exercise price of $11.50.

No fractional Common Shares will be issued upon exercise. If, upon exercise, a holder would be entitled to receive a fractional interest in a share, Roivant will round down to the nearest whole number of the number of Common Shares to be issued to the holder. If, at the time of redemption, the Warrants are exercisable for a security other than the Common Shares pursuant to the warrant agreement (for instance, if Roivant is not the surviving company in an initial business combination), the Warrants may be exercised for such security. At such time as the Warrants become exercisable for a security other than the Common Shares, Roivant (or surviving company) will use its commercially reasonable efforts to register under the Securities Act the security issuable upon the exercise of the Warrants.

Redemption Procedures. A holder of a Warrant may notify Roivant in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.9% or 9.8% (as specified by the holder) of the Common Shares issued and outstanding immediately after giving effect to such exercise.

Anti-dilution Adjustments. If the number of outstanding Common Shares is increased by a share subdivisions, share capitalization or dividend payable in Common Shares, or by a split-up of Common Shares or other similar event, then, on the effective date of such share subdivision, share capitalization, split-up or similar event, the number of Common Shares issuable on exercise of each Warrant will be increased in proportion to such increase in the outstanding shares of Common Shares. A rights offering to holders of Common Shares entitling holders to purchase Common Shares at a price less than the "historical fair market value" (as defined below) will be deemed a dividend of a number of Common Shares equal to the product of (i) the number of Common Shares actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Common Shares) and (ii) one minus the quotient of (x) the price per Roivant Common Share paid in such rights offering and (y) the historical fair market value. For these purposes, (i) if the rights offering is for securities convertible into or exercisable for Common Shares, in determining the price payable for Common Shares, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) "historical fair market value" means the volume-weighted average price of Common Shares as reported during the 10 trading day period ending on the trading day prior to the first date on which the Common Shares trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of Common Shares on account of such Common Shares (or other securities into which the Warrants are convertible), other than (a) as described above, (b) any cash dividends or cash distributions which, when combined on a per share basis with all other cash dividends and cash distributions paid on the Common Shares during the 365-day period ending on the date of declaration of such dividend or distribution does not exceed $0.50 (as adjusted to appropriately reflect any other adjustments and excluding cash dividends or cash distributions that resulted in an adjustment to the exercise price or to the number of Common Shares issuable on exercise of each warrant) but only with respect to the amount of the aggregate cash dividends or cash distributions equal to or less than $0.50 per share, (c) to satisfy the redemption rights of the holders of Common Shares in connection with a proposed initial business combination, (d) to satisfy the redemption rights of the holders of Common Shares in connection with a shareholder vote to amend our amended and restated bye-laws (A) to modify the substance or timing of our obligation to allow redemption in connection with an initial business combination or to redeem 100% of Common Shares if Roivant does not complete an initial business combination within 24 months from the closing of the initial public offering or (B) with respect to any other provision relating to shareholders' rights or pre-initial business combination activity, or (e) in connection with the redemption of Common Shares upon our failure to complete an initial business combination, then the Warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each Roivant Common Share in respect of such event.

If the number of outstanding Common Shares is decreased by a consolidation, combination, reverse share split or reclassification of Common Shares or other similar event, then, on the effective date of such consolidation, combination, reverse share split, reclassification or similar event, the number of Common Shares issuable on exercise of each Roivant Warrant will be decreased in proportion to such decrease in outstanding Common Shares.

Whenever the number of Common Shares purchasable upon the exercise of the Warrants is adjusted, as described above, the Warrant exercise price will be adjusted by multiplying the Warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of Common Shares purchasable upon the exercise of the Warrants immediately prior to such adjustment and (y) the denominator of which will be the number of Common Shares so purchasable immediately thereafter.

In addition, if (x) Roivant issues additional Common Shares or equity-linked securities for capital raising purposes in connection with the closing of an initial business combination at an issue price or effective issue price of less than $9.20 per Roivant Common Share (with such issue price or effective issue price to be

determined in good faith by our board of directors and, in the case of any such issuance to our sponsor or its affiliates, without taking into account any shares held by the MAAC Sponsor or its affiliates, as applicable, prior to such issuance (the "Newly Issued Price"), (y) the aggregate gross proceeds from such issuances represent more than 60% of the total equity proceeds, and interest thereon, available for the funding of an initial business combination on the date of the completion of an initial business combination (net of redemptions), and (z) the volume-weighted average trading price of Common Shares during the 20 trading day period starting on the trading day prior to Closing (such price, the "Market Value") is below $9.20 per share, the exercise price of the Warrants will be adjusted (to the nearest cent) to be equal to 115% of the higher of the Market Value and the Newly Issued Price, and the $10.00 and $18.00 per share redemption trigger prices described adjacent to "Redemption of Warrants When the Price per Roivant Common Share Equals or Exceeds $18.00" and "Redemption of Warrants When the Price per Roivant Common Share Equals or Exceeds $10.00" will be adjusted (to the nearest cent) to be equal to 100% and 180% of the higher of the Market Value and the Newly Issued Price, respectively.

In case of any reclassification or reorganization of the outstanding Common Shares (other than those described above or that solely affects the par value of such Common Shares), or in the case of any merger or consolidation of Roivant with or into another corporation (other than a consolidation or merger in which Roivant is the continuing corporation and that does not result in any reclassification or reorganization of our outstanding Common Shares), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of Roivant as an entirety or substantially as an entirety in connection with which Roivant is dissolved, the holders of the Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Warrants and in lieu of the Common Shares immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of Common Shares or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Warrants would have received if such holder had exercised their Warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of Common Shares in such a transaction is payable in the form of Common Shares in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the Roivant Warrant properly exercises the Roivant Warrant within thirty days following public disclosure of such transaction, the Warrant exercise price will be reduced as specified in the warrant agreement based on the Black-Scholes value (as defined in the warrant agreement) of the warrant. The purpose of such exercise price reduction is to provide additional value to holders of the Warrants when an extraordinary transaction occurs during the exercise period of the Warrants pursuant to which the holders of the Warrants otherwise do not receive the full potential value of the Warrants.

The Warrants are issued in registered form under a warrant agreement between American Stock Transfer & Trust Company, LLC as warrant agent, and us.

The warrant agreement provides that the terms of the Warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correct any mistake, including to conform the provisions of the warrant agreement to the description of the terms of the Warrants and the warrant agreement set forth in this prospectus, or defective provision (ii) amending the provisions relating to cash dividends on Common Shares as contemplated by and in accordance with the warrant agreement or (iii) adding or changing any provisions with respect to matters or questions arising under the warrant agreement as the parties to the warrant agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the Warrants, provided that the approval by the holders of at least 50% of the then-outstanding public Warrants is required to make any change that adversely affects the interests of the registered holders of public Warrants. You should review a copy of the warrant agreement for a complete description of the terms and conditions applicable to the Warrants.

The Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed

and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of Warrants being exercised. The Warrant holders do not have the rights or privileges of holders of Common Shares and any voting rights until they exercise their Warrants and receive Common Shares. After the issuance of Common Shares upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by shareholders.

No fractional shares will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, Roivant will, upon exercise, round down to the nearest whole number, the number of Common Shares to be issued to the Warrant holder.

Private Placement Warrants

The Private Placement Warrants (including the Common Shares issuable upon exercise of the Private Placement Warrants) will not be transferable, assignable or salable until 30 days after the completion of an initial business combination (except pursuant to limited exceptions) and they will not be redeemable by Roivant so long as they are held by our sponsor or its permitted transferees (except as otherwise set forth herein). Our sponsor, or its permitted transferees, have the option to exercise the Private Placement Warrants on a cashless basis. Except as described below, the Private Placement Warrants have terms and provisions that are identical to those of the Warrants sold as part of the units in the initial public offering. If the Private Placement Warrants are held by holders other than our sponsor or its permitted transferees, the Private Placement Warrants will be redeemable by Roivant in all redemption scenarios and exercisable by the holders on the same basis as the Warrants included in the units being sold in the initial public offering.

If holders of the Private Placement Warrants elect to exercise them on a cashless basis, they would pay the exercise price by surrendering his, her or its Warrants for that number of Common Shares equal to the quotient obtained by dividing (x) the product of the number of Common Shares underlying the Warrants, multiplied by the excess of the "historical fair market value" (defined below) over the exercise price of the Warrants by (y) the historical fair market value. For these purposes, the "historical fair market value" shall mean the average last reported sale price of the Common Shares for the 10 trading days ending on the third trading day prior to the date on which the notice of Warrant exercise is sent to the warrant agent. The reason that Roivant has agreed that these Warrants will be exercisable on a cashless basis so long as they are held by our sponsor and its permitted transferees is because it is not known at this time whether they will be affiliated with Roivant following a business combination. If they remain affiliated with us, their ability to sell our securities in the open market will be significantly limited. Roivant expects to have policies in place that restrict insiders from selling our securities except during specific periods of time. Even during such periods of time when insiders will be permitted to sell our securities, an insider cannot trade in our securities if he or she is in possession of material non-public information. Accordingly, unlike public shareholders who could exercise their Warrants and sell the Common Shares received upon such exercise freely in the open market in order to recoup the cost of such exercise, the insiders could be significantly restricted from selling such securities. As a result, Roivant believes that allowing the holders to exercise such Warrants on a cashless basis is appropriate.

Certain Provisions of Bermuda Law

We have been designated by the Bermuda Monetary Authority as a non-resident for Bermuda exchange control purposes. This designation allows us to engage in transactions in currencies other than the Bermuda dollar, and there are no restrictions on our ability to transfer funds (other than funds denominated in Bermuda dollars) in and out of Bermuda or to pay dividends to U.S. residents who are holders of Common Shares.

The Bermuda Monetary Authority has given its consent for the issue and free transferability of all of the Common Shares that are the subject of this offering to and between residents and non-residents of Bermuda for exchange control purposes, provided our shares remain listed on an appointed stock exchange, which includes

Nasdaq. Approvals or permissions given by the Bermuda Monetary Authority do not constitute a guarantee by the Bermuda Monetary Authority as to our performance or our creditworthiness. Accordingly, in giving such consent or permissions, neither the Bermuda Monetary Authority nor the Registrar of Companies in Bermuda shall be liable for the financial soundness, performance or default of our business or for the correctness of any opinions or statements expressed in this prospectus. Certain issues and transfers of Common Shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of Common Shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.

In accordance with Bermuda law, share certificates are only issued in the names of companies, partnerships or individuals. In the case of a shareholder acting in a special capacity (for example as a trustee), certificates may, at the request of the shareholder, record the capacity in which the shareholder is acting. Notwithstanding such recording of any special capacity, we are not bound to investigate or see to the execution of any such trust.

Exchange Controls

The permission of the Bermuda Monetary Authority is required, pursuant to the provisions of the Exchange Control Act 1972 and related regulations, for all issuances and transfers of shares (which includes Common Shares) of Bermuda companies to or from a non-resident of Bermuda for exchange control purposes, other than in cases where the Bermuda Monetary Authority has granted a general permission. The Bermuda Monetary Authority, in its notice to the public dated June 1, 2005, has granted a general permission for the issue and subsequent transfer of any securities of a Bermuda company from or to a non-resident of Bermuda for exchange control purposes for so long as any “Equity Securities” of the company (which would include Common Shares) are listed on an “Appointed Stock Exchange” (which would include Nasdaq). Certain issues and transfers of Common Shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of Common Shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.

Transfer Agent

The transfer agent for the Common Shares is American Stock Transfer & Trust Company, LLC.

Listing of Common Stock

The Common Shares are listed on The Nasdaq Global Market under the symbol “ROIV.”

PLAN OF DISTRIBUTION

We are registering the resale by the Holders of 17,407,773 Common Shares.

We will not receive any of the proceeds from the sale of the securities by the Holders. The aggregate proceeds to the Holders will be the purchase price of the securities less any discounts and commissions borne by the Holders.

The Common Shares beneficially owned by the Holders covered by this prospectus may be offered and sold from time to time by the Holders. The term "Holders" includes donees, pledgees, transferees or other successors in interest selling securities received after the date of this prospectus from a Holder as a gift, pledge, partnership distribution or other transfer. The Holders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The Holders may sell their Common Shares by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of Nasdaq;
- through trading plans entered into by a Holder pursuant to Rule 10b5-1 under the Exchange Act, that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- to or through underwriters or broker-dealers;
- in "at the market" offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- in privately negotiated transactions;
- in options transactions;
- through a combination of any of the above methods of sale; or
- any other method permitted pursuant to applicable law.

In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the Holders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of Common Shares in the course of hedging transactions, and broker-dealers or other financial institutions may engage in short sales of Common Shares in the course of hedging the positions they assume with Holders. The Holders may also sell Common Shares short and redeliver the shares to close out such short positions. The Holders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-

dealer or other financial institution of shares offered by this prospectus, which shares such broker- dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Holders may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

A Holder may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by any Holder or borrowed from any Holder or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from any Holder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment). In addition, any Holder may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In effecting sales, broker-dealers or agents engaged by the Holders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Holders in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the Holders and any broker-dealers who execute sales for the Holders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any profits realized by the Holders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the Holders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the Holders and their affiliates. In addition, we will make copies of this prospectus available to the Holders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Holders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallowed or paid to any dealer, and the proposed selling price to the public.

Restrictions to Sell

Refer to below under “Securities Act Restrictions on Resale of Securities – Lock-up Provisions.”

SECURITIES ACT RESTRICTIONS ON RESALE OF SECURITIES

Rule 144

Pursuant to Rule 144 under the Securities Act ("Rule 144"), a person who has beneficially owned restricted Common Shares for at least six months would, subject to the restrictions noted in the section below, be entitled to sell their securities provided that (i) such person is not deemed to have been an affiliate of us at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as we were required to file reports) preceding the sale.

Persons who have beneficially owned restricted Common Shares for at least six months but who are affiliates of us at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of Common Shares then outstanding; or
- the average weekly reported trading volume of such securities during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by our affiliates under Rule 144 are also limited by manner of sale provisions and notice requirements and to the availability of current public information about us.

Lock-up Provisions

Our bye-laws contain a lock-up provision (the "Bye-laws Lock-up") which provides that, without the prior consent of the board of directors of Roivant and subject to certain customary exceptions, each holder will not, for a period ending 180 calendar days following the effective time of the Merger, lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any (a) Common Shares or (b) any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Shares (including Common Shares underlying incentive equity awards), in each case that are outstanding immediately prior to the Effective Time. For the avoidance of doubt, such restriction will not apply to any Common Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Shares held by or on behalf of any stockholder of MAAC (other than a stockholder of MAAC who is also a Roivant shareholder that did not purchase MAAC Shares directly from MAAC) prior to, or received in connection with, the closing of the transactions contemplated by the Business Combination Agreement, including Common Shares issued in connection with the PIPE Financing.

In addition, concurrently with the signing of the Business Combination Agreement, Roivant and certain Roivant equityholders entered into the Registration Rights Agreement. The Registration Rights Agreement contains a lock-up provision agreements (the "Registration Rights Agreement Lock-up" and, together with the Lock-up Agreements and the Bye-laws Lock-up, the "Lock-ups"), which provides that, without the prior consent of the board of directors of Roivant and subject to certain customary exceptions, each holder will not, for a period ending 180 calendar days following the closing of the Business Combination, lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Shares (including Common Shares underlying incentive equity awards), in each case that were outstanding immediately prior to the closing of the Business Combination.

Form S-8 Registration Statement

We have filed a registration statement on Form S-8 under the Securities Act to register the Common Shares issued or issuable under our equity incentive plans. The Form S-8 registration statement become effective automatically upon filing on October 8, 2021. The initial registration statement on Form S-8 covered approximately 167,200,000 Common Shares. Because the offering of such shares is registered, they can be sold in the public market upon issuance, subject to the lock-up provisions described above and Rule 144 limitations applicable to affiliates and vesting restrictions.

MATERIAL UNITED STATES TAX CONSIDERATIONS

The following discussion is a description of material U.S. federal income tax considerations to U.S. Holders (as defined below) of the Common Shares as a consequence of the ownership and disposition of Common Shares.

This discussion applies only to a U.S. Holder that holds the Common Shares as capital assets for U.S. federal income tax purposes (generally, property held for investment). In addition, it does not describe all of the U.S. federal income tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including any alternative minimum tax considerations, the potential application of the provisions of the Code known as the Medicare contribution tax and tax considerations applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities that use mark-to-market method of tax accounting;
- persons holding the Common Shares as part of a straddle, wash sale, hedging transaction, conversion transaction or integrated transaction or entering into a constructive sale with respect to such securities;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- persons that are subject to the "applicable financial statement" rules under Section 451(b) of the Code;
- entities classified as partnerships for U.S. federal income tax purposes and their partners;
- tax-exempt entities, "individual retirement accounts" or "Roth IRAs";
- persons actually or constructively owning ten percent or more of the combined voting power or value of our Common Shares;
- persons owning shares in connection with a trade or business conducted outside of the United States;
- persons who acquire Common Shares pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to Common Shares being taken into account in an applicable financial statement.

If a partnership (or other entity that is classified as a partnership for U.S. federal income tax purposes) holds the Common Shares the tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding the Common Shares and partners in such partnerships should consult their tax advisor as to the particular tax consequences of the ownership and disposition of Common Shares by the partnership.

As used here in, a "U.S. Holder" is a person that for U.S. federal income tax purposes is a beneficial owner of Common Shares and:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

This discussion is based on the Code, administrative pronouncements, judicial decisions, and final, temporary and proposed Treasury regulations, all as of the date hereof, and of which is subject to change, possibly with retroactive effect. We have not sought, and will not seek, a ruling from the IRS as to any U.S. federal income tax consequences described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. This discussion does not address any U.S. federal taxes (such as estate or gift taxes) other than income taxes, nor does it address any state, local or non-U.S. tax considerations. U.S. Holders should consult their tax advisors concerning the U.S. federal, state, local and foreign tax consequences of the ownership and disposition of Common Shares in their particular circumstances.

EACH U.S. HOLDER SHOULD CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH HOLDER OF THE OWNERSHIP AND DISPOSITION OF COMMON SHARES.

Dividends and Other Distributions on the Common Shares

Subject to the PFIC rules discussed below under the heading "—Passive Foreign Investment Company Rules," distributions (including, for the avoidance of doubt and for the purpose of the balance of this discussion, deemed distributions) on Common Shares will generally be taxable as a dividend for U.S. federal income tax purposes to the extent paid from Roivant's current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of Roivant's current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. Holder's adjusted tax basis in its Common Shares. Any remaining excess will be treated as gain realized on the sale or other disposition of the Common Shares and will be treated as described below under the heading "—Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Shares." The amount of any such distribution will include any amounts withheld by us (or another applicable withholding agent). Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders generally will be taxed at the lower applicable long-term capital gains rate if the Common Shares are readily tradable on an established securities market in the United States (such as the Nasdaq, where the Common Shares are currently listed) or Roivant is eligible for benefits under an applicable tax treaty with the United States, and, in each case, Roivant is not treated as a PFIC with respect to such U.S. Holder at the time the dividend was paid or in the preceding year and provided certain holding period requirements are met. The amount of any dividend distribution paid in foreign currency will be the U.S. dollar amount calculated by reference to the applicable exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Amounts taxable as dividends generally will be treated as income from sources outside the U.S. and will, depending on the circumstances of the U.S. Holder, be "passive" or "general" category income which, in either case, is treated separately from other types of income for purposes of computing the foreign tax credit allowable to such U.S. Holder. The rules governing foreign tax credits are complex and U.S. Holders are urged to consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, a U.S. Holder may, in certain circumstances, deduct foreign taxes in computing their taxable income, subject to generally applicable limitations under U.S. law. Generally, an election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. Notwithstanding the foregoing, if (a) Roivant is 50% or more owned, by vote or value, by U.S. persons and (b) at least 10% of Roivant's earnings and profits are attributable to sources within the U.S., then for foreign tax credit purposes, a portion of Roivant's dividends would be treated as derived from sources within the U.S. In such case, with respect to any dividend paid for any taxable year, the U.S.-source ratio of such dividends for foreign tax credit purposes would be equal to the portion of Roivant's earnings and profits from sources within the U.S. for such taxable year, divided by the total amount of Roivant's earnings and profits for such taxable year.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Shares

Subject to the PFIC rules discussed below under the heading "—Passive Foreign Investment Company Rules," upon any sale, exchange or other taxable disposition of Common Shares, a U.S. Holder generally will recognize gain or loss in an amount equal to the difference between (i) the sum of (x) the amount of cash and (y) the fair market value of any other property, received in such sale, exchange or other taxable disposition and (ii) the U.S. Holder's adjusted tax basis in such Common Shares, as calculated in U.S. dollars. Any such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder's holding period for such Common Shares exceeds one year. Long-term capital gain realized by a non-corporate U.S. Holder generally will be taxable at a reduced rate. The deductibility of capital losses is subject to limitations.

Any gain or loss recognized on the sale, exchange or other taxable disposition of Common Shares generally will be U.S.-source income or loss for purposes of computing the foreign tax credit allowable to a U.S. Holder. Consequently, a U.S. Holder may not be able to claim a credit for any non-U.S. tax imposed upon a disposition of Common Shares unless such credit can be applied (subject to applicable limitations) against tax due on other income treated as derived from foreign sources. Prospective U.S. Holders should consult their tax advisors as to the foreign tax credit implications of such sale, exchange or other taxable disposition of Common Shares.

Passive Foreign Investment Company Rules

The treatment of U.S. Holders of Common Shares could be materially different from that described above if Roivant is treated as a PFIC for U.S. federal income tax purposes.

A foreign (i.e., non-U.S.) corporation will be classified as a PFIC for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (ii) at least 50% of its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes, among other things, dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets.

Roivant's status as a PFIC will depend on the nature and composition of its income and the nature, composition and value of its assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset. If Roivant is a CFC (determined by disregarding certain downward attribution rules) and not publicly traded for the relevant taxable year, however, the test will be applied based on the adjusted basis of Roivant's assets.

The New Regulations modify certain of the rules described above. Such modifications include, for example, permitting asset value to be determined more frequently than on a quarterly basis and treating a non-U.S. corporation as publicly traded for a taxable year if the stock of such corporation is publicly traded, other than in de minimis quantities, for at least twenty trading days during such taxable year.

The New Regulations generally apply to taxable years of shareholders beginning on or after January 14, 2021. A shareholder, however, may choose to apply such rules for any open taxable year beginning before January 14, 2021, provided that, with respect to a non-U.S. corporation being tested for PFIC status, the shareholder consistently applies certain of the provisions of the New Regulations and certain other Treasury regulations for such year and all subsequent years. Investors who are U.S. Holders should consult their own tax advisors regarding the impact and applicability of the New Regulations.

Because our Common Shares should be considered to be "publicly traded" for the current taxable year that ends on March 31, 2022, we should apply the 50% passive asset test using the fair market value of its assets. This determination, however, is subject to uncertainty. In addition, Roivant's status may also depend, in part, on how quickly it utilizes its cash on-hand and cash from future financings in its business.

Based on the foregoing, with respect to the taxable year that ended on March 31, 2021, Roivant believes that it was not a PFIC (based in part on its belief that it was not classified as a CFC in the taxable year that ended on March 31, 2021) and presently does not anticipate that it will be a PFIC based upon the expected value of its assets, including any goodwill and intangible assets, and the expected nature and composition of its income and assets. However, Roivant's status as a PFIC is a fact-intensive determination made on an annual basis, and it cannot provide any assurances regarding its PFIC status for the current or future taxable years. Roivant's U.S. counsel expresses no opinion with respect to Roivant's PFIC status for the current or future taxable years. Roivant will determine its PFIC status for each taxable year and make such determination available to U.S. Holders.

Roivant has implemented structures and arrangements intended to mitigate the possibility that it will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether Roivant is classified as a PFIC in the current and future taxable years. In addition, recently finalized U.S. Treasury regulations, the impact of which Roivant is continuing to assess, may also adversely affect the treatment of these structures and arrangements with respect to its PFIC status. Although Roivant's PFIC status is determined annually, an initial determination that Roivant is a PFIC will generally apply for subsequent years to a U.S. Holder who held Common Shares while Roivant was a PFIC, whether or not Roivant meets the test for PFIC status in those subsequent years. If Roivant is determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder of Common Shares and the U.S. Holder did not make an applicable PFIC election (or elections), as further described below under the heading "—PFIC Elections," for the first taxable year of Roivant in which it was treated as a PFIC, and in which the U.S. Holder held (or was deemed to hold) such Common Shares, such U.S. Holder generally will be subject to special and adverse rules. Such rules apply to (i) any gain recognized by the U.S. Holder on the sale or other disposition of its Common Shares (which may include gain realized by reason of transfers of Common Shares that would otherwise qualify as nonrecognition transactions for U.S. federal income tax purposes) and (ii) any "excess distribution" made to the U.S. Holder (generally, any distributions to such U.S. Holder during a taxable year of the U.S. Holder that are greater than 125% of the average annual distributions received by such U.S. Holder in respect of the Common Shares during the three preceding taxable years of such U.S. Holder or, if shorter, the portion of such U.S. Holder's holding period for the Common Shares that preceded the taxable year of the distribution).

Under these rules:

- the U.S. Holder's gain or excess distribution will be allocated ratably over the U.S. Holder's holding period for the Common Shares;
- the amount allocated to the U.S. Holder's taxable year in which the U.S. Holder recognized the gain or received the excess distribution, or to the period in the U.S. Holder's holding period before the first day of Roivant's first taxable year in which Roivant is a PFIC, will be taxed as ordinary income;
- the amount allocated to other taxable years (or portions thereof) of the U.S. Holder and included in its holding period will be taxed at the highest tax rate in effect for that year and applicable to the U.S. Holder without regard to the U.S. Holder's other items of income and loss for such year; and
- an additional tax equal to the interest charge generally applicable to underpayments of tax will be imposed on the U.S. Holder with respect to the tax attributable to each such other taxable year of the U.S. Holder.

PFIC Elections

If Roivant is a PFIC and Common Shares constitute "marketable stock," a U.S. Holder may avoid the adverse PFIC tax consequences discussed above with respect to its Common Shares if such U.S. Holder makes a mark-to-market election with respect to such shares for the first taxable year in which it holds (or is deemed to hold) Common Shares and each subsequent taxable year. Such U.S. Holder generally will include for each of its

taxable years as ordinary income the excess, if any, of the fair market value of its Common Shares at the end of such year over its adjusted basis in its Common Shares. These amounts of ordinary income would not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains. The U.S. Holder also will recognize an ordinary loss in respect of the excess, if any, of its adjusted basis of its Common Shares over the fair market value of its Common Shares at the end of its taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). The U.S. Holder's basis in its Common Shares will be adjusted to reflect any such income or loss amounts, and any further gain recognized on a sale or other taxable disposition of its Common Shares will be treated as ordinary income.

The mark-to-market election is available only for "marketable stock," generally, stock that is regularly traded on a national securities exchange that is registered with the Securities and Exchange Commission, including the Nasdaq (on which Common Shares are currently listed), or on a foreign exchange or market that the IRS determines has rules sufficient to ensure that the market price represents a legitimate and sound fair market value. If made, a mark-to-market election would be effective for the taxable year for which the election was made and for all subsequent taxable years unless the Common Shares cease to qualify as "marketable stock" for purposes of the PFIC rules or the IRS consents to the revocation of the election. U.S. Holders are urged to consult their tax advisors regarding the availability and tax consequences of a mark-to-market election with respect to Common Shares under their particular circumstances.

Alternatively, if Roivant is determined to be a PFIC, a U.S. Holder may avoid the adverse PFIC tax consequences described above in respect of Common Shares by making and maintaining a timely and valid qualified electing fund ("QEF") election (if eligible to do so). If a U.S. Holder makes a QEF election with respect to a PFIC, the U.S. Holder will be taxed on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is a PFIC. If a U.S. Holder makes a QEF election with respect to the Common Shares, any distributions paid by Roivant out of its earnings and profits that were previously included in the U.S. Holder's income under the QEF election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its Common Shares by an amount equal to any income included under the QEF election and will decrease its tax basis by any amount distributed on the Common Shares that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of Common Shares in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the Common Shares, as determined in U.S. dollars. U.S. Holders should note that if they make QEF elections with respect to Roivant, they may be required to pay U.S. federal income tax with respect to their Common Shares for any taxable year significantly in excess of any cash distributions received on the Common Shares for such taxable year. U.S. Holders should consult their tax advisers regarding making QEF elections in their particular circumstances. A U.S. Holder generally may make a separate election to defer the payment of taxes on undistributed income inclusions under the QEF rules, but if deferred, any such taxes will be subject to an interest charge.

A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder's timely filed U.S. federal income tax return. However, Roivant currently does not intend to provide information necessary for U.S. Holders to make QEF elections with respect to Common Shares.

Related PFIC Rules

If Roivant is a PFIC and, at any time, has a foreign subsidiary that is classified as a PFIC, a U.S. Holder generally would be deemed to own a proportionate amount of the shares of such lower-tier PFIC, and generally could incur liability for the deferred tax and interest charge described above if Roivant receives a distribution from, or disposes of all or part of its interest in, the lower-tier PFIC, or the U.S. Holder otherwise was deemed to have disposed of an interest in the lower-tier PFIC. Roivant currently does not intend to cause any lower-tier PFIC to provide to a U.S. Holder the information that may be required to make or maintain a QEF election with respect to the lower-tier PFIC. A mark-to-market election generally would not be available with respect to such lower-tier PFIC. U.S. Holders are urged to consult their tax advisors regarding the tax issues raised by lower-tier PFICs.

A U.S. Holder that owns (or is deemed to own) shares in a PFIC during any taxable year of the U.S. Holder, may have to file an IRS Form 8621 (whether or not a QEF or mark-to-market election is made) and to provide such other information as may be required by the U.S. Treasury Department. Failure to do so, if required, will extend the statute of limitations applicable to such U.S. Holder until such required information is furnished to the IRS.

The rules dealing with PFICs and with the mark-to-market and QEF elections are very complex and are affected by various factors in addition to those described above. Accordingly, U.S. Holders of Common Shares are urged to consult their own tax advisors concerning the application of the PFIC rules to Roivant securities under their particular circumstances.

Additional Reporting Requirements

Certain U.S. Holders holding specified foreign financial assets with an aggregate value in excess of the applicable dollar thresholds are required to report information to the IRS relating to Common Shares, subject to certain exceptions (including an exception for Common Shares held in accounts maintained by U.S. financial institutions), by attaching a complete IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their tax return for each year in which they hold Common Shares. Substantial penalties apply to any failure to file IRS Form 8938 and the period of limitations on assessment and collection of U.S. federal income taxes will be extended in the event of a failure to comply. U.S. Holders are urged to consult their tax advisors regarding the effect, if any, of these rules on the ownership and disposition of Common Shares.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting, and may be subject to backup withholding. Backup withholding generally will not apply, however, to a U.S. Holder if (i) the U.S. Holder is a corporation or other exempt recipient or (ii) the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

THE U.S. FEDERAL INCOME TAX DISCUSSION SET FORTH ABOVE MAY NOT BE APPLICABLE TO YOU DEPENDING UPON YOUR PARTICULAR SITUATION. YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES TO YOU OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF COMMON SHARES INCLUDING THE TAX CONSEQUENCES UNDER STATE, LOCAL, ESTATE, FOREIGN AND OTHER TAX LAWS AND TAX TREATIES AND THE POSSIBLE EFFECTS OF CHANGES IN U.S. OR OTHER TAX LAWS.

MATERIAL UNITED KINGDOM TAX CONSIDERATIONS

In the opinion of Davis Polk & Wardwell London LLP, the following is a description of material United Kingdom tax considerations relating to the ownership and disposal of the Common Shares applicable to a non-UK Holder. The comments set out below are based on current United Kingdom tax law as applied in England and Wales and HM Revenue & Customs, or HMRC, practice (which may not be binding on HMRC) as at the date of this summary, both of which are subject to change, possibly with retrospective effect. They are intended as a general guide and, save where expressly stated otherwise, apply only to absolute beneficial owners of the Common Shares who are (i) individuals not resident in the United Kingdom for United Kingdom tax purposes who do not hold Common Shares for the purposes of a trade, profession, or vocation which they carry on in the United Kingdom through a branch or agency, or (ii) companies not resident in the United Kingdom for United Kingdom tax purposes which do not hold the Common Shares for the purpose of a trade carried on in the United Kingdom through a permanent establishment in the United Kingdom, together, "non-UK Holders."

This summary does not address all possible tax consequences relating to an investment in the Common Shares. Certain categories of holders, including those falling outside the category described above (such as those who are resident in the United Kingdom for United Kingdom tax purposes), those carrying on certain financial activities, those subject to specific tax regimes or benefitting from certain reliefs or exemptions, those connected with Roivant and those for whom the shares are employment-related securities may be subject to special rules and this summary does not apply to such holders and any general statements made in this disclosure do not take them into account.

Potential investors should satisfy themselves prior to investing as to the overall tax consequences, including, specifically, the consequences under United Kingdom tax law and HMRC practice of the acquisition, ownership and disposal of the Common Shares in their own particular circumstances by consulting their own tax advisors.

EACH HOLDER SHOULD CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH HOLDER OF THE OWNERSHIP AND DISPOSAL OF COMMON SHARES AND EXERCISE, INCLUDING THE EFFECTS OF UNITED KINGDOM TAX LAWS.

United Kingdom Taxation of Dividends

Roivant will not be required to withhold amounts on account of United Kingdom tax at source when paying a dividend in respect of Common Shares to a non-UK Holder.

Non-UK Holders who hold their Common Shares as an investment should not be subject to United Kingdom tax in respect of any dividends.

United Kingdom Taxation of Capital Gains

Disposal of Common Shares

An individual who is a non-UK Holder will generally not be liable to United Kingdom capital gains tax on capital gains realized on the disposal of his or her Common Shares.

A company that is a non-UK Holder will generally not be liable for United Kingdom corporation tax on chargeable gains realized on the disposal of its Common Shares.

An individual non-UK Holder who is only temporarily a non-UK resident for United Kingdom tax purposes will, in certain circumstances, become liable to United Kingdom tax on capital gains in respect of gains realized while he or she was not resident in the United Kingdom.

United Kingdom Stamp Duty ("stamp duty") and Stamp Duty Reserve Tax ("SDRT")

No stamp duty or SDRT is expected to be payable on the transfer of Common Shares, subject to the comments below.

Stamp duty will in principle be payable on any instrument that transfers Common Shares that is executed in the United Kingdom or that relates to any property situated, or to any matter or thing done or to be done, in the United Kingdom. Holders of Common Shares should be aware that, even where such an instrument is in principle subject to stamp duty, stamp duty is not required to be paid unless it is necessary to rely on the instrument for legal purposes, for example to register a change of ownership or in litigation in a United Kingdom court. Provided that the Common Shares are not registered in any register maintained in the United Kingdom, any agreement to transfer Common Shares will not be subject to SDRT. Roivant currently does not intend that any register of its Common Shares will be maintained in the United Kingdom.

LEGAL MATTERS

Conyers Dill & Pearman Limited have passed upon the validity of the Common Shares offered by this prospectus and certain other legal matters related to this prospectus.

EXPERTS

The consolidated financial statements of Roivant Sciences Ltd. at March 31, 2021 and 2020, and for each of the two years in the period ended March 31, 2021, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1, including exhibits, under the Securities Act of 1933, as amended, with respect to the securities offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our securities, you should refer to the registration statement and our exhibits.

In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public on a website maintained by the SEC located at www.sec.gov. We also maintain a website at https://roivant.com. Through our website, we make available, free of charge, annual, quarterly and current reports, proxy statements and other information as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Roivant Sciences Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Roivant Sciences Ltd. (the Company) as of March 31, 2021 and 2020, the related consolidated statements of operations, comprehensive (loss) income, shareholders' equity and redeemable noncontrolling interest and cash flows for each of the two years in the period ended March 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Iselin, New Jersey
June 30, 2021, except for Note 1(C), as to which the date is
December 22, 2021

ROIVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2021	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 2,055,044	$ 2,183,207
Restricted cash	77,701	2,275
Other current assets	54,250	33,763
Total current assets	2,186,995	2,219,245
Property and equipment, net	14,749	8,962
Operating lease right-of-use assets	62,279	64,970
Restricted cash, net of current portion	8,931	83,770
Investments measured at fair value	188,978	93,445
Long-term investment	100,563	—
Other assets	27,197	6,659
Total assets	$ 2,589,692	$ 2,477,051
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 20,550	$ 10,306
Accrued expenses	76,936	68,621
Operating lease liabilities	12,313	7,839
Deferred consideration liability	100,000	—
Other current liabilities	9,162	5,352
Total current liabilities	218,961	92,118
Liability instruments measured at fair value	67,893	102,373
Operating lease liabilities, noncurrent	62,384	64,452
Long-term debt (includes $150,100 and $89,100 accounted for under the fair value option at March 31, 2021 and 2020, respectively)	170,280	108,592
Other liabilities	8,169	821
Total liabilities	527,687	368,356
Commitments and contingencies (Note 14)		
Redeemable noncontrolling interest	22,491	22,491
Shareholders' equity(1)		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 651,576,293 and 628,779,048 shares issued and outstanding at March 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	3,814,805	3,143,739
Subscription receivable	(100,000)	—
Accumulated deficit	(1,918,462)	(1,109,228)
Accumulated other comprehensive income (loss)	1,445	(2,349)
Shareholders' equity attributable to Roivant Sciences Ltd.	1,797,788	2,032,162
Noncontrolling interests	241,726	54,042
Total shareholders' equity	2,039,514	2,086,204
Total liabilities, redeemable noncontrolling interest and shareholders' equity	$ 2,589,692	$ 2,477,051

(1) Retroactively restated for the stock subdivision as described in Note 1.

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended March 31,	
	2021	2020
Revenue, net	$ 23,795	$ 67,689
Operating expenses:		
Cost of revenues	2,057	1,131
Research and development	832,758	263,217
General and administrative	259,878	335,766
Total operating expenses	1,094,693	600,114
Loss from operations	(1,070,898)	(532,425)
Change in fair value of investments	(95,533)	136,005
Change in fair value of debt and liability instruments	29,845	(13,722)
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(115,364)	(107,344)
Other expense, net	8,701	13,622
Loss from continuing operations before income taxes	(898,547)	(560,986)
Income tax expense	1,686	7,124
Loss from continuing operations, net of tax	(900,233)	(568,110)
Income from discontinued operations, net of tax	—	1,578,426
Net (loss) income	(900,233)	1,010,316
Net loss attributable to noncontrolling interests	(90,999)	(190,193)
Net (loss) income attributable to Roivant Sciences Ltd.	$ (809,234)	$ 1,200,509
Amounts attributable to Roivant Sciences Ltd.:		
Loss from continuing operations, net of tax	$ (809,234)	$ (519,394)
Income from discontinued operations, net of tax	—	1,719,903
Net (loss) income attributable to Roivant Sciences Ltd.	$ (809,234)	$ 1,200,509
Basic and diluted net (loss) income per common share:(1)		
Basic and diluted loss from continuing operations	$ (1.28)	$ (0.93)
Basic and diluted income from discontinued operations	$ —	$ 2.68
Basic and diluted net (loss) income per common share	$ (1.28)	$ 1.75
Basic and diluted weighted average shares outstanding:(1)		
Basic	630,046,720	640,944,987
Diluted	630,046,720	640,944,987

(1) Retroactively restated for the stock subdivision as described in Note 1.

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Years Ended March 31,	
	2021	2020
Net (loss) income	$ (900,233)	$ 1,010,316
Other comprehensive income (loss):		
Foreign currency translation adjustment	3,826	(5,536)
Total other comprehensive income (loss)	3,826	(5,536)
Comprehensive (loss) income	(896,407)	1,004,780
Comprehensive loss attributable to noncontrolling interests	(90,967)	(190,862)
Comprehensive (loss) income attributable to Roivant Sciences Ltd.	$ (805,440)	$ 1,195,642

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statement of Shareholders' Equity and Redeemable Noncontrolling Interest
(in thousands, except share data)

	Redeemable Noncontrolling Interest	Shareholders' Equity(1)							
		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount						
Balance at March 31, 2019	$ 50,130	624,904,938	$ —	$3,024,172	$ —	$ 2,518	$ (2,309,737)	$ 170,216	$ 887,169
Issuance of subsidiary common shares, net	—	—	—	59,052	—	—	—	58,606	117,658
Issuance of subsidiary common shares to the Company	—	—	—	(9,962)	—	—	—	9,962	—
Purchase of subsidiary common shares	—	—	—	(62,913)	—	—	—	(2,631)	(65,544)
Issuance of subsidiary convertible and redeemable preferred stock, net	27,491	—	—	—	—	—	—	—	—
Purchase of subsidiary convertible and redeemable preferred stock	(55,130)	—	—	(77,777)	—	—	—	—	(77,777)
Issuance of subsidiary warrants	—	—	—	—	—	—	—	907	907
Exercise of subsidiary stock options	—	—	—	875	—	—	—	532	1,407
Issuance of the Company's common shares, net	—	78,867,360	—	999,193	—	—	—	—	999,193
Repurchase of common shares and other equity instruments	—	(74,986,605)	—	(990,014)	—	—	—	—	(990,014)
Sale of interests in subsidiaries	—	—	—	—	—	—	—	(43,398)	(43,398)
Issuance of equity by subsidiary upon Business Combination and recapitalization	—	—	—	69,379	—	—	—	35,307	104,686
Issuance of equity by subsidiary to the Company upon Business Combination and recapitalization	—	—	—	(2,559)	—	—	—	2,559	—
Conversion of subsidiary convertible promissory notes	—	—	—	21,928	—	—	—	11,159	33,087
Issuance of equity instruments	—	—	—	24,842	—	—	—	—	24,842
Settlement in equity of liability-classified instruments	—	—	—	13,119	—	—	—	—	13,119
Deconsolidation of subsidiary	—	—	—	—	—	—	—	(46,483)	(46,483)
Capital contributions to majority-owned subsidiaries	—	—	—	(4,699)	—	—	—	4,699	—
Share-based compensation	—	(6,645)	—	79,103	—	—	—	43,469	122,572
Foreign currency translation adjustment	—	—	—	—	—	(4,867)	—	(669)	(5,536)
Net income (loss)	—	—	—	—	—	—	1,200,509	(190,193)	1,010,316
Balance at March 31, 2020	$ 22,491	628,779,048	$ —	$3,143,739	$ —	$ (2,349)	$ (1,109,228)	$ 54,042	$ 2,086,204
Issuance of the Company's common shares	—	21,077,155	—	301,744	—	—	—	—	301,744
Issuance of subsidiary common shares, net	—	—	—	324,995	(100,000)	—	—	231,102	456,097
Issuance of subsidiary common shares to the Company	—	—	—	(11,692)	—	—	—	11,692	—
Exercise of subsidiary stock options and vesting of subsidiary restricted stock units	—	—	—	522	—	—	—	385	907
Deconsolidation of subsidiary	—	—	—	—	—	—	—	(3,054)	(3,054)
Consolidation of unconsolidated entity	—	—	—	—	—	—	—	9,178	9,178
Repurchase of equity awards	—	—	—	(113)	—	—	—	—	(113)
Cash contribution to majority-owned subsidiaries	—	—	—	(1,642)	—	—	—	1,642	—
Share-based compensation	—	1,720,090	—	57,252	—	—	—	27,706	84,958
Foreign currency translation adjustment	—	—	—	—	—	3,794	—	32	3,826
Net loss	—	—	—	—	—	—	(809,234)	(90,999)	(900,233)
Balance at March 31, 2021	$ 22,491	651,576,293	$ —	$3,814,805	$ (100,000)	$ 1,445	$ (1,918,462)	$ 241,726	$ 2,039,514

(1) Retroactively restated for the stock subdivision as described in Note 1.

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended March 31, 2021	2020
Cash flows from operating activities:		
Net (loss) income	$ (900,233)	$ 1,010,316
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Acquired in-process research and development	351,523	16,405
Unrealized foreign currency translation adjustment	3,826	(5,536)
Share-based compensation	84,958	122,572
Gain on sale of business	—	(1,985,949)
Change in fair value of investments	(95,533)	136,005
Change in fair value of debt and liability instruments	29,845	(13,722)
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(115,364)	(107,344)
Loss from equity method investment	3,750	21,386
Other	13,152	31,821
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Accounts payable	3,752	6,598
Accrued expenses	9,225	14,845
Deferred consideration liability	100,000	—
Operating lease liabilities	(5,497)	(8,419)
Other	(35,542)	2,272
Net cash used in operating activities	(552,138)	(758,750)
Cash flows from investing activities:		
Proceeds from sale of business, net of cash disposed	—	1,772,191
Cash disposed upon deconsolidation of subsidiary	(19,085)	(20,049)
Cash acquired upon consolidation of unconsolidated entity	21,439	—
Investments in unconsolidated entities	(28,250)	(36,300)
Purchase of marketable securities	—	(32,076)
Maturity of marketable securities	—	16,440
Acquisitions, net of cash acquired	—	(500)
Purchase of property and equipment	(5,806)	(4,916)
Net cash (used in) provided by investing activities	(31,702)	1,694,790
Cash flows from financing activities:		
Proceeds from issuance of the Company’s common shares, net	—	999,193
Repurchase of common stock and equity awards	(113)	(990,014)
Proceeds from issuance of liability instruments	—	101,567
Proceeds from issuance of subsidiary common shares, net	455,756	117,658
Proceeds from issuance of equity by subsidiary upon Business Combination and recapitalization	—	105,930
Purchase of subsidiary common shares	—	(65,544)
Proceeds from issuance of subsidiary convertible and redeemable preferred stock, net	—	28,455
Purchase of subsidiary convertible and redeemable preferred stock	—	(132,907)
Proceeds from subsidiary debt financings, net	—	83,781
Repayment of long-term debt and convertible debt by subsidiary	—	(32,063)
Payment of deferred offering costs	(286)	(3,082)
Payment for debt maintenance fee by subsidiary	—	(300)
Proceeds from exercise of subsidiary stock options	907	1,407
Net cash provided by financing activities	456,264	214,081
Net change in cash, cash equivalents and restricted cash	(127,576)	1,150,121
Cash, cash equivalents and restricted cash at beginning of period	2,269,252	1,119,131
Cash, cash equivalents and restricted cash at end of period	$ 2,141,676	$ 2,269,252

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Cash Flows (Continued)
(in thousands)

	Years Ended March 31, 2021	2020
Non-cash investing and financing activities:		
Operating lease right-of-use assets obtained and exchanged for operating lease liabilities	$ 5,491	$56,025
Operating lease right-of-use assets and operating lease liabilities, including amounts reclassified from other current liabilities and other liabilities to operating lease liabilities, recognized upon the adoption of ASC 842, Leases, on April 1, 2019	$ —	$43,026
Subscription receivable related to issuance of subsidiary common shares	$100,000	$ —
Conversion of subsidiary convertible promissory notes to common shares	$ —	$32,500
Other	$ (960)	$ 3,601
Supplemental disclosure of cash paid:		
Income taxes paid	$ 4,076	$ 4,936
Interest paid	$ 2,017	$12,158

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.

Notes to Consolidated Financial Statements

Note 1—Description of Business and Liquidity

(A) Description of Business

Roivant Sciences Ltd., inclusive of its consolidated subsidiaries (the "Company" or "RSL"), aims to improve health by rapidly delivering innovative medicines and technologies to patients. The Company does this by building biotech and healthcare technology companies ("Vants") and deploying technology to drive greater efficiency in research and development and commercialization. In addition to biopharmaceutical subsidiaries, the Company also builds technology Vants focused on improving the process of developing and commercializing medicines. The Company was founded on April 7, 2014 as a Bermuda exempted limited company.

The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company's subsidiaries are wholly owned subsidiaries and majority-owned or controlled subsidiaries. Refer to Note 3, "Investments" for further discussion of the Company's investments in unconsolidated entities.

(B) Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2021, the Company had cash and cash equivalents of approximately $2.1 billion and its accumulated deficit was approximately $1.9 billion. For the years ended March 31, 2021 and 2020, the Company incurred losses from continuing operations of $900.2 million and $568.1 million, respectively. The Company has historically financed its operations primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates or take other steps to conserve capital. The Company expects its existing cash and cash equivalents will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these consolidated financial statements.

(C) Business Combination with MAAC and Stock Subdivision

On September 30, 2021 (the "Closing Date"), in accordance with the Business Combination Agreement, as amended (the "Business Combination Agreement"), RSL completed its previously announced business combination with Montes Archimedes Acquisition Corp. ("MAAC"), through the merger of RSL's wholly-owned subsidiary, Rhine Merger Sub, Inc., with MAAC (the "Merger"), with MAAC surviving the Merger as a wholly owned subsidiary of RSL. As MAAC does not represent a business for accounting purposes and its primary asset represents cash and cash equivalents, the business combination with MAAC was treated as an equity contribution in exchange for the issuance of RSL shares. The net assets of MAAC were stated at historical cost, with no goodwill or other intangible assets recorded.

On the Closing Date prior to the effective time of the Merger, RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination Agreement. The shares, equity awards

and net loss per share available to holders of the Company's common stock, prior to the business combination with MAAC, have been retroactively restated as shares reflecting the fixed exchange ratio.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation and Principles of Consolidation

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30, and December 31.

The accompanying audited consolidated financial statements and notes thereto have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Any references in these notes to applicable accounting guidance are meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates
("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of RSL and the subsidiaries in which it has a controlling financial interest, most often through a majority voting interest. All intercompany balances and transactions have been eliminated in consolidation.

For consolidated entities where the Company owns or is exposed to less than 100% of the economics, the Company records net loss attributable to noncontrolling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in the respective operations by the noncontrolling parties. The Company presents noncontrolling interests as a component of shareholders' equity on its consolidated balance sheets.

The Company accounts for changes in its ownership interest in its subsidiaries while control is retained as equity transactions. The carrying amount of the noncontrolling interest is adjusted to reflect the change in RSL's ownership interest in the subsidiary. Any difference between the fair value of the consideration received or paid and the amount by which the noncontrolling interest is adjusted is recognized within shareholders' equity attributable to RSL.

Additionally, the Company concluded that the disposition of RSL's ownership interests in Myovant Sciences Ltd. ("Myovant"), Urovant Sciences Ltd. ("Urovant"), Enzyvant Therapeutics Ltd. ("Enzyvant"), Altavant Sciences Ltd. ("Altavant"), and Spirovant Sciences Ltd. ("Spirovant") (collectively, the "Sumitovant Vants"), pursuant to the transaction agreement entered into with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") on October 31, 2019 (the "Sumitomo Transaction Agreement") that closed on December 27, 2019 (the "Sumitomo Transaction"), met the requirements to be presented as discontinued operations. As such, results relating to the transferred interests prior to disposition are classified as discontinued operations in prior period consolidated financial statements. See Note 5, "Sumitomo Transaction Agreement" and Note 6, "Discontinued Operations" for further discussion. Certain prior year amounts were reclassified to conform to current year presentation.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The

Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses, contingent liabilities, share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of March 31, 2021 and through the issuance of these consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

(C) Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights.

(D) Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents. The Company maintains cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

(E) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Restricted cash classified as a current asset consists of the amount held in escrow relating to the Sumitomo Transaction (see Note 5, "Sumitomo Transaction Agreement") and the legally restricted non-interest bearing deposit account relating to the Company's corporate credit card program. Restricted cash classified as a long-term asset consists of restricted deposit accounts related to irrevocable standby letters of credit.

Cash as reported in the accompanying consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash as presented on the accompanying consolidated balance sheets as follows (in thousands):

	March 31, 2021	March 31, 2020
Cash and cash equivalents	$ 2,055,044	$ 2,183,207
Restricted cash	86,632	86,045
Cash, cash equivalents and restricted cash	$ 2,141,676	$ 2,269,252

(F) Trade Receivables, Net

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in customer credit profiles. The Company reserves against trade receivables for

estimated losses that may arise from a customer's inability to pay and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was de minimis as of March 31, 2021 and 2020. Trade receivables, net is included in "Other current assets" on the accompanying consolidated balance sheets.

(G) Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses any litigation or other claims it may confront to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

(H) Property and Equipment

Property and equipment, consisting primarily of computers, equipment, furniture and fixtures, software, and leasehold improvements, is recorded at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation of property and equipment is recorded using the straight-line method over the estimated useful lives of the related assets once the asset has been placed in service. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter. The following table provides the range of estimated useful lives used for each asset type:

Property and Equipment	Estimated Useful Life
Computers	3 years
Equipment	5 years
Furniture and fixtures	7 years
Software	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. Recoverability is measured by comparison of the book values of the assets to the future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

(I) Investments

For investments in entities over which the Company has significant influence but do not meet the requirements for consolidation and for which the Company has not elected the fair value option, the Company applies the equity method of accounting with the Company's share of the underlying income or loss of such entities reported in "Other expense, net" on the consolidated statements of operations. The Company applies the equity method to investments in common stock and to other investments in entities that have risk and reward characteristics that are substantially similar to an investment in the investee's common stock.

Investments in equity securities may also be accounted for using (i) the fair value option if elected, (ii) fair value through earnings if fair value is readily determinable or (iii) for equity investments without readily determinable

fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

The Company has elected the fair value option to account for certain investments over which the Company has significant influence. The Company believes the fair value option best reflects the underlying economics of the investment. See Note 3, “Investments.”

(J) Research and Development Expenses

Research and development (“R&D”) costs are expensed as incurred. Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as R&D. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. R&D costs primarily consist of the intellectual property and R&D materials acquired and expenses from third parties who conduct R&D activities on behalf of the Company.

The Company evaluates in-licensed agreements for in-process research and development projects (“IPR&D”) to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as R&D expense in its consolidated statements of operations. The Company initially recognizes contingent consideration in an asset acquisition at fair value. The carrying value of contingent consideration is subsequently adjusted when the contingency is resolved and is paid or becomes payable.

(K) General and Administrative Expenses

General and administrative (“G&A”) expenses consist primarily of employee-related expenses for G&A personnel, including those responsible for the identification and acquisition or in-license of new drug candidates as well as for overseeing Vant operations and facilitating the use of the Company’s platform and technologies at Vants. G&A expenses also consist of legal and accounting fees, consulting services and other operating costs relating to corporate matters and daily operations. G&A expenses include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates along with costs incurred relating to the integration of new technologies.

(L) Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company’s deferred tax assets will be realizable. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

(M) Share-Based Compensation

Share-based awards to employees, directors, and consultants, including stock options, restricted stock units, performance options and capped value appreciation rights, are measured at fair value on the date of the grant and that fair value is recognized as share-based compensation expense in the Company's consolidated statements of operations over the requisite service period of the respective award. The estimated fair value of awards that contain performance conditions is expensed when the Company concludes that it is probable that the performance condition will be achieved. The Company may grant awards with graded-vesting features. When such awards have only service vesting requirements, the Company elected to record share-based compensation expense on a straight-line basis. If awards with graded-vesting features contain performance or market conditions, then the Company records share-based compensation expense using the accelerated attribution method.

The Company measures the fair value of its stock options that only have service vesting requirements or performance-based options without market conditions using the Black-Scholes option pricing model. For performance-based awards with market conditions, the Company determines the fair value of the awards as of the grant date using a Monte Carlo simulation model.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company's common shares. Since the Company has no option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. The Company accounts for pre-vesting award forfeitures when they occur.

As part of the valuation of share-based compensation under the Black-Scholes option pricing model, it is necessary for the Company to estimate the fair value of its common shares for RSL and privately held Vants. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Company exercises reasonable judgment and considers numerous objective and subjective factors to determine its best estimate of the fair value of its common shares. The estimation of the fair value of the common shares considers factors including the following: the prices of the Company's common shares sold to investors in arm's length transactions, the estimated present value of the Company's future cash flows; the Company's business, financial condition and results of operations; the Company's forecasted operating performance; the illiquid nature of the Company's common shares; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions.

(N) Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis

for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include shares of common stock of Arbutus Biopharma Corporation ("Arbutus"); shares of Arbutus's Series A participating convertible preferred shares ("Arbutus Preferred Shares"); shares of common stock of Sio Gene Therapies Inc. ("Sio"); liability instruments issued, including options granted to Sumitomo (the "Sumitomo Options") to purchase all, or 75% in one case, of RSL's ownership interests in certain subsidiaries under the Sumitomo Transaction Agreement; deferred consideration liability; its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus and Sio common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. The Arbutus Preferred Shares held by the Company are classified as Level 2 as the fair value of such preferred shares is determined based upon the quoted market price of Arbutus common stock into which such preferred shares are convertible. The liability instruments issued, including the Sumitomo Options, are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. Cash, accounts payable, and deferred consideration liability are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The deferred consideration liability is based on a fixed monetary amount, and payment is based solely on the passage of time. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant Sciences Ltd. (together with its wholly owned subsidiaries, "Dermavant"), which is stated at amortized cost, approximates fair value based on current interest rates for similar types of borrowings and therefore is included in Level 2 of the fair value hierarchy. Long-term debt issued by Dermavant for which the fair value option has been elected is included in Level 3 of the fair value hierarchy as the assumptions and estimates used in the valuation are unobservable in the market.

(O) Foreign Currency

Assets and liabilities of foreign operations are translated using exchange rates in effect at the balance sheet date and their results of operations are translated using average exchange rates for the year. Certain transactions of the Company and its subsidiaries are denominated in currencies other than their functional currency. Adjustments resulting from the translation of the financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholders' equity. Foreign exchange transaction gains and losses are included in "Other expense, net" in the Company's statements of operations.

(P) Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for its arrangements, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property:* If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.
- *Milestone payments:* At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.
- *Royalties and commercial milestone payments:* For arrangements that include sales-based royalties, including commercial milestone payments based on a pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Revenue is also generated by certain technology-focused Vants from subscription and service-based fees recognized for the use of certain technology developed by these Vants. Subscription revenue is recognized ratably over the contract period.

(Q) Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” (“ASU No. 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU No. 2016-13 replaces

the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU No. 2016-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The adoption of ASU No. 2016-13 on April 1, 2020 did not have a material impact on the Company's consolidated financial statements.

(R) Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging —Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU No. 2020-06"). ASU No. 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. ASU No. 2020-06 also removes certain settlement conditions that are required for equity contracts to qualify for the derivatives scope exception, which will permit more equity contracts to qualify for it. Either a modified retrospective transition method or a fully retrospective transition method is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted no earlier than the fiscal year beginning after December 15, 2020. The adoption of ASU No. 2020-06 is not expected to have a material impact on the Company's consolidated financial statements.

Note 3—Investments

(A) Investments Measured at Fair Value

Investment in Arbutus

RSL owns 16,013,540 shares of common stock of Arbutus and 1,164,000 Arbutus Preferred Shares that are mandatorily convertible into shares of Arbutus common stock on October 18, 2021 subject to conversion earlier upon a sale, merger or other transaction considered a fundamental change of control of Arbutus. The Arbutus Preferred Shares are non-voting and are convertible into common shares of Arbutus based on the subscription price plus 8.75% per annum, compounded annually, divided by a conversion price of $7.13 per share (which represented a 15% premium to the closing price of $6.20 per share on September 29, 2017). RSL's investments in Arbutus have been measured using the fair value option. Due to the Company's significant influence over operating and financial policies, Arbutus is considered a related party of the Company.

After conversion of the Arbutus Preferred Shares into common shares, based on the number of Arbutus's common shares outstanding on October 2, 2017, the Company would hold 49.90% of Arbutus's common shares. In addition, the Company agreed to a four-year standstill to not acquire greater than 49.99% of common shares or securities convertible into common shares of Arbutus.

At March 31, 2021 and 2020, the aggregate fair value of the Company's investment in Arbutus was $129.4 million and $39.2 million, respectively, with the Company recognizing an unrealized gain on its investments in Arbutus of $90.2 million and an unrealized loss of $99.9 million in the accompanying consolidated statements of operations for the years ended March 31, 2021 and 2020, respectively. The fair value of the common stock and preferred shares held by the Company was determined using the closing price of Arbutus's common stock on March 31, 2021 and 2020 of $3.33 and $1.01, respectively.

Investment in Sio

Following the completion of Sio's underwritten public offering in February 2020, RSL's ownership interest fell below 50.0%. As such, the Company no longer has a controlling financial interest in Sio. Accordingly, the Company deconsolidated Sio in February 2020. Due to the Company's significant influence over operating and financial policies, Sio remains a related party of the Company following deconsolidation. As the Company still has the ability to exercise significant influence over the operating and financial policies of Sio, the Company has determined that its retained interest represents an equity method investment after the date of deconsolidation. Upon deconsolidation, the retained interest was recorded at fair market value based on the closing price of Sio's common stock. The Company recognized a gain on deconsolidation of $107.3 million in the accompanying consolidated statements of operations for the year ended March 31, 2020. The fair value option was elected to continuously remeasure the investment to fair value each reporting period after the initial measurement.

At March 31, 2021 and 2020, the fair value of the Company's investment in Sio was $48.5 million and $45.3 million, respectively, with the Company recognizing an unrealized gain on its investment in Sio of $3.2 million and an unrealized loss of $31.6 million in the accompanying consolidated statements of operations for the years ended March 31, 2021 and 2020, respectively. The fair value of common shares held by the Company was determined using the closing price of Sio's common stock on March 31, 2021 and 2020 of $2.61 and $2.44, respectively.

Other Investment

The Company holds an additional equity investment that is measured using the fair value option. The fair value of this investment was $11.1 million and $8.9 million as of March 31, 2021 and 2020, respectively.

(B) Investment Accounted for Using Measurement Alternative

Investment in Datavant

In April 2020, Datavant Holdings, Inc. ("Datavant") completed an initial round of a Series B equity raise by which 13,411,311 Series B preferred shares were issued in April 2020 for gross proceeds of $27.2 million, including 1,065,234 Series B preferred shares issued and sold to RSL for a total purchase price of $2.5 million and 1,800,253 Series B shares issued relating to the conversion of certain liability instruments. As a result of this transaction, along with a restructuring of Datavant's equity classes, RSL no longer controls Datavant. As such, the Company deconsolidated Datavant as of April 2020. Due to the Company's significant influence over operating and financial policies, Datavant remains a related party of the Company following deconsolidation. Upon deconsolidation, the Company recorded its investment in Datavant based on the fair value of Datavant preferred shares held of $99.0 million. The Company accounts for its investment in Datavant using the measurement alternative to fair value. The investment will be remeasured upon future observable price changes in orderly transactions or upon impairment, if any. The Company recognized a gain on deconsolidation of $86.5 million in the accompanying consolidated statements of operations for the year ended March 31, 2021. In July 2020, Datavant issued and sold 639,140 Series B preferred shares to RSL at a price consistent with that of the initial round of Datavant's Series B equity raise. At March 31, 2021, the carrying value of the Company's investment in Datavant was $100.6 million.

Note 4—Asset Acquisitions and License Agreements

During the years ended March 31, 2021 and 2020, the Company, directly or indirectly through Vants, completed the following key asset acquisitions and license agreements. The Company evaluated the below agreements, except the collaboration and license agreement entered into between Dermavant and Japan Tobacco Inc. that is evaluated separately below, and determined that the acquired assets did not meet the definition of a business as substantially all the fair value of the assets acquired were concentrated in a single asset or group of similar assets and/or the acquired assets were not capable of producing outputs due to the lack of an assembled workforce and early stage of development and thus, each transaction was accounted for as an asset acquisition.

The Company then evaluated whether each in-process research and development asset had an alternative future use and concluded it did not. As a result, the Company recorded the consideration attributable to in-process research and development under the below agreements as research and development expense in the accompanying consolidated statements of operations for the years ended March 31, 2021 and 2020.

Dermavant

In August 2018, Dermavant acquired the worldwide rights (other than with respect to certain rights in China) to tapinarof, an investigational therapeutic aryl hydrocarbon receptor modulating agent for the treatment of psoriasis and atopic dermatitis, from GlaxoSmithKline Intellectual Property Development Ltd. and Glaxo Group Limited (collectively "GSK") pursuant to an asset purchase agreement (the "GSK Agreement"). GSK previously acquired rights to a predecessor formulation of tapinarof from Welichem Biotech Inc. ("Welichem") pursuant to an asset purchase agreement between GSK and Welichem entered into in May 2012 (the "Welichem Agreement"). Under the GSK Agreement, Dermavant made an upfront payment of £150.0 million (approximately $191 million) and agreed to a contingent payment of £100.0 million (approximately $133 million) upon the first approval of an NDA by the FDA for a product that contains tapinarof. Dermavant assumed responsibility for all obligations under the Welichem Agreement, including payment of up to C$180.0 million (approximately $137 million) in potential development and commercial milestones. The purchase was funded in part by a $117.5 million borrowing from NovaQuest Co-Investment Fund VIII, L.P. ("NovaQuest"), an affiliate of NovaQuest Capital Management, LLC, as described in Note 8, "Long-Term Debt." In connection with the GSK Agreement, Dermavant and GSK have entered into a clinical manufacturing and supply agreement for tapinarof pursuant to which Dermavant will obtain supply of tapinarof for clinical trials on a cost-plus basis. In May 2019, Dermavant achieved a development and regulatory milestone under the GSK Agreement, which resulted in a C$30.0 million (approximately $23 million) milestone payment that Dermavant subsequently paid to Welichem in August 2019. The milestone payment was recorded as research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2020.

In January 2020, Dermavant entered into a collaboration and license agreement with Japan Tobacco Inc. ("JT") for exclusive rights to develop, register, and market tapinarof in Japan for the treatment of dermatological diseases and conditions, including psoriasis and atopic dermatitis. In conjunction with this agreement, JT executed an exclusive license agreement with its subsidiary, Torii Pharmaceutical Co., Ltd., for co-development and commercialization of tapinarof in Japan. Under the terms of the license agreement, Dermavant received a nonrefundable, upfront payment of $60.0 million in January 2020 and may receive up to $53.0 million upon the achievement of certain development milestones for tapinarof for the treatment of psoriasis and atopic dermatitis. In addition, Dermavant will have the right to receive royalties based on product sales of tapinarof in the indications.

The Company evaluated the collaboration and license agreement and concluded that JT is a customer. The Company's performance obligations under the agreement are the following: (i) an exclusive license to JT of the right to develop, register and market tapinarof in Japan and (ii) the associated transfer to JT of technology and know-how related to the license. The Company determined that the monetary value of participation in the Joint Steering Committee under the agreement was immaterial in the context of the contract and therefore was disregarded when identifying the performance obligations. The Company determined that the exclusive license is not capable of being distinct from the associated technology transfer because the customer cannot benefit from or utilize the license without the technology and know-how transfer and as such does not have standalone value as JT cannot benefit from the exclusive license without the associated technology and know-how transfer. Accordingly, the Company concluded that these performance obligations should be combined into a single performance obligation.

Based on management's evaluation, the non-refundable, up-front payment of $60.0 million constituted the amount of consideration to be included in the transaction price. The remaining $53.0 million of consideration related to potential development and regulatory approval milestones constitutes variable consideration and has

not been recognized because of the inherent uncertainty of the occurrence of the future events and because it is highly susceptible to factors outside of the Company's control. Any consideration related to potential royalty payments will be recognized when the related sales occur, since these amounts have been determined to relate predominantly to the license granted to JT and therefore are recognized at the later of when the performance obligations are satisfied or the related sales occur. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. Upon transfer of the technology and know-how related to the license, the Company recognized the $60.0 million non-refundable upfront payment as license revenue in the accompanying consolidated statements of operations for the year ended March 31, 2020.

Genevant

In July 2020, RSL increased its investment in Genevant Sciences Ltd. ("Genevant") as part of a recapitalization transaction (the "Recapitalization"). Genevant, an entity focused on the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by Arbutus' proprietary lipid nanoparticle and ligand conjugate delivery technologies, was created in April 2018 as part of an agreement between RSL and Arbutus. As part of the initial transaction entered into in April 2018, RSL contributed $38.7 million in cash, including transaction costs, for an equity ownership interest in Genevant. Prior to the Recapitalization, RSL accounted for its investment in Genevant under the equity method of accounting as it had determined that it was not the primary beneficiary of Genevant since it did not have the power to direct its most significant activities. Additionally, RSL made additional investments in the form of promissory notes issued by Genevant amounting to $20.1 million aggregate principal amount outstanding (the "Genevant Outstanding Notes") prior to the Recapitalization. RSL applied its share of losses relating to its equity method investment in Genevant against the Company's carrying value of its investment in Genevant's common shares and against the carrying value of the Genevant Outstanding Notes. The carrying value of RSL's investment in Genevant was reduced to zero prior to the Recapitalization.

Pursuant to the Recapitalization, the following transactions were completed:

- Genevant issued 74,272,043 common shares to RSL for an aggregated purchase price of $20.5 million;
- $15.1 million aggregate principal amount of the Genevant Outstanding Notes were converted into 54,526,549 common shares; and
- Genevant issued 9,057,566 common shares to Arbutus for an aggregated purchase price of $2.5 million.

Following the Recapitalization, RSL held an 82.9% controlling interest in Genevant.

Concurrent with the Recapitalization, the composition of Genevant's Board of Directors was restructured to include two directors designated by RSL and one director who is a senior officer of Genevant.

As a result of the Recapitalization and changes to the bye-laws, RSL determined that it controls the most significant activities of Genevant and is the primary beneficiary of Genevant following the Recapitalization. As such, RSL began consolidating Genevant into the Company's consolidated financial statements from the date of the Recapitalization. The Company evaluated the acquired set of assets and activities and determined that the acquired set did not meet the definition of a business and thus the transaction was not considered a business combination.

The transactions completed as part of the Recapitalization represent an acquisition achieved in stages, which required the remeasurement of RSL's previously held interest in Genevant. As such, RSL's investments in Genevant were remeasured to fair value of $28.8 million, also resulting in a gain of $28.8 million in the accompanying consolidated statements of operations for the year ended March 31, 2021. Along with the fair value of noncontrolling interests in Genevant of $9.2 million and cash paid of $20.5 million for common shares of Genevant as part of the Recapitalization, total consideration paid was $58.5 million. Of this amount,

$41.4 million was attributed to in-process research and development, which was determined by the Company to have not reached technological feasibility and therefore have no alternative future use. Accordingly, the Company recorded $41.4 million as research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2021.

Proteovant

In November 2020, Proteovant Sciences, Inc. (formerly known as Pharmavant 5, Inc.) ("ProteoVant") entered into a stock purchase agreement to acquire Oncopia Therapeutics, Inc. ("Oncopia"), a preclinical biotechnology
company developing small molecule protein degraders primarily against certain oncology targets. Upfront proceeds to Oncopia's shareholders were $105.0 million, prior to certain adjustments in accordance with the terms of the agreement. Proteovant is also obligated to make future development and commercial milestone payments of up to $100.0 million for the first product targeting each of the two specified initial targets, and up to $51.0 million for the first product targeting each of certain specified additional molecular targets. Additionally, the Company's investments in promissory notes issued by Oncopia for an aggregate principal amount of $11.5 million were settled through either conversion to equity or cancellation.

Oncopia's intellectual property was developed by the University of Michigan laboratory run by Oncopia's co-founder (the "Co-Founder"). In connection with Proteovant's acquisition, Oncopia amended and restated its existing license agreements with the University of Michigan. Under the new license agreement, Oncopia will be obligated to make future development and commercial milestone payments of up to $8.6 million for the first product for each molecular target covered by intellectual property included in the agreement, in addition to paying tiered royalties on net sales ranging from low- to mid-single digits, subject to certain adjustments.

The Co-Founder's lab at the University of Michigan had been providing on-going discovery and optimization services to Oncopia under a sponsored research agreement (the "SRA"). Immediately after closing the acquisition, Oncopia extended the SRA through at least December 31, 2023, and expanded the potential molecular targets to be pursued under the SRA. As revised, Oncopia is obligated to pay the University of Michigan approximately $15.5 million under the SRA.

Lastly, in connection with the acquisition of Oncopia, the Co-Founder entered into an agreement with the Company to serve as a consultant. In exchange for these services, the Company has agreed to grant the Co-Founder RSL restricted stock units for which the majority will vest upon achievement of development milestones for products directed to targets for which no milestones are payable to Oncopia shareholders and the remaining portion will be subject to time-based service requirements. All of these restricted stock units are subject to a liquidity requirement to vest. The Company will also make a cash payment to the Co-Founder upon achievement of development milestones for each such product.

During the year ended March 31, 2021, the Company recorded $116.5 million, relating to the net upfront cash payment of $101.2 million, settlement of promissory notes receivable, including accrued interest, of $11.9 million, and fair value of future contingent consideration payments of $3.4 million, as research and development expense in the accompanying consolidated statements of operations.

In December 2020, RSL, Proteovant and SK, Inc. (formerly known as SK Holdings Co., Ltd.) ("SK") entered into a subscription agreement (the "Subscription Agreement") pursuant to which SK agreed to make a $200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date. In January 2021, in accordance with the terms of the Subscription Agreement, SK made the first payment of $100.0 million to Proteovant. A second $100.0 million payment is expected to be made by SK to Proteovant on or about July 12, 2021, the date six months from the closing date. The second $100.0 million payment is classified as a subscription receivable in the accompanying consolidated balance sheets and consolidated statements of shareholders' equity and redeemable noncontrolling interest as of March 31, 2021.

Affivant

In November 2020, RSL and its indirect subsidiary Affivant Sciences GmbH ("Affivant") entered into a licensing and strategic collaboration agreement with Affimed N.V. ("Affimed") to develop and commercialize novel innate cell engagers for multiple cancer targets in exchange for consideration that includes $40.0 million in upfront cash and pre-paid R&D funding and $20.0 million of newly issued shares in RSL. Affimed could receive further short-term proceeds in the form of option fees contingent on the commencement of additional programs contemplated under the agreement. Affimed is eligible to receive up to an additional approximately $2.0 billion in milestones over time upon achievement of specified development, regulatory and commercial milestones, as well as tiered royalties on net sales.

Acquisition of Silicon Therapeutics

In March 2021, the Company completed the acquisition of the business of Silicon Therapeutics, LLC ("SiTX"), a physics-driven computational drug discovery company, for total consideration of approximately $450.0 million, with additional cash payments payable subject to the satisfaction of certain regulatory and commercial milestones. This acquisition did not include one of SiTX's subsidiaries, Silicon SWAT, Inc. Approximately $350.0 million of the consideration was payable primarily in the Company's common stock at or near closing of the acquisition (the "First Tranche"). At closing of the acquisition, the Company issued 21,409,764 common shares and paid approximately $14.0 million in cash, net of cash received, to SiTX after giving effect to certain transaction adjustments and holdbacks. The remainder of the First Tranche is expected to be paid in a combination of common shares and cash as certain holdbacks are released. Approximately $100.0 million (the "Second Tranche Consideration") is payable to SiTX on the earlier of (x) approximately 30 to 60 days following the public listing of the Company's common shares, in either cash or common shares (at the Company's election), and (y) 12 months following the closing of the acquisition, in cash.

The transaction was accounted for as an asset acquisition as substantially all of the fair value of the assets acquired were concentrated in a single asset, IPR&D related to the computational drug discovery platform that designs and develops small molecule therapeutics. For accounting purposes, the fair value of consideration transferred was $402.4 million, consisting of $281.7 million relating to the fair value of common shares issued upfront and expected to be issued shortly thereafter; $105.1 million relating to the fair value of liabilities due to the sellers, including the Second Tranche Consideration, future contingent consideration payments, and closing consideration to be paid in cash; and cash of $15.6 million paid at closing. Of this amount, $399.6 million was attributed to IPR&D, which was determined to have no alternative future use. Accordingly, the Company recorded $399.6 million as research and development expense in the accompanying consolidated statement of operations for the year ended March 31, 2021.

In connection with the transaction, the vesting of certain outstanding SiTX share-based compensation awards held by employees of SiTX was discretionarily accelerated at closing. As a result, the Company recorded share-based compensation expense of $23.5 million in the accompanying consolidated statements of operations for the year ended March 31, 2021.

In addition, certain share-based compensation awards of SiTX were exchanged with restricted common stock of the Company, subject to certain service-based vesting requirements, with a fair value of $22.6 million. Of this amount, $15.6 million was attributed to precombination service and therefore included in the total fair value of consideration transferred. Refer to Note 11, "Share-Based Compensation," for additional detail regarding this restricted common stock.

Note 5—Sumitomo Transaction Agreement

On December 27, 2019 (the "Sumitomo Closing Date"), RSL and Sumitomo completed the transactions contemplated by the Sumitomo Transaction Agreement. Pursuant to the Sumitomo Transaction Agreement, RSL transferred its entire ownership interest in Myovant, Urovant, Enzyvant, Altavant, and Spirovant to a newly formed, wholly-owned entity ("Sumitovant").

RSL's ownership interest in Sumitovant was then transferred to Sumitomo, such that following the Sumitomo Closing Date, Sumitovant and its subsidiaries, including the Sumitovant Vants, were each directly or indirectly owned by Sumitomo. Additionally, in connection with the Sumitomo Transaction Agreement, RSL (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of RSL's ownership interests in six other subsidiaries (Dermavant, Genevant, Lysovant Sciences Ltd. ("Lysovant"), Metavant Sciences Ltd. ("Metavant"), Roivant Asia Cell Therapy Holdings Ltd. ("Cytovant Parent"), and Sinovant Sciences HK Limited ("Sinovant")), (ii) (a) transferred the proprietary technology platform DrugOme to Sumitomo (for which RSL retains a perpetual royalty free license for internal use) and (b) licensed the Digital Innovation technology platform to Sumitomo (for which both parties retain ongoing access) and (iii) transferred 78,867,360 common shares of RSL to Sumitomo. On the Sumitomo Closing Date, the Company received approximately $2.9 billion in cash, resulting in a gain of $2.0 billion after taking into account all of the components of the transaction.

Additionally, on the Sumitomo Closing Date, $75.0 million of the consideration was deposited into a segregated escrow account for the purpose of fulfilling indemnification obligations of RSL that may become due to Sumitomo. Upon the expiration of the escrow period, being 18 months from the Sumitomo Closing Date, any remaining escrow funds will be disbursed to RSL. As of March 31, 2021, the Company does not believe that a reasonably possible loss of the funds in the escrow account exists. As such, the full escrow amount of $75.0 million was recorded by the Company as restricted cash on the accompanying consolidated balance sheets as of March 31, 2021. In connection with the Sumitomo Transaction, RSL's board of directors approved a repurchase of RSL's equity securities for up to $1.0 billion of the proceeds received from Sumitomo. Refer to Note 10, "Shareholders' Equity and Redeemable Noncontrolling Interest" for further detail.

In conjunction with the Sumitomo Transaction, certain employees of the Company became employees of Sumitovant or its subsidiaries. The Company issued certain instruments with an aggregate fair value of $39.1 million to these employees, of which $24.8 million was classified within shareholders' equity and $14.3 million was classified as a liability. The liability classified awards were subsequently surrendered and exchanged for cash and other newly issued equity as part of the repurchase in March 2020. The remaining instruments vest based on the achievement of time-based, performance or liquidity event requirements. As of March 31, 2021 and 2020, there were 5,458,543 and 5,504,124 outstanding instruments, respectively, held by Sumitovant employees for which aggregate fair value was recorded against the gain on sale of business.

In June 2021, RSL completed a transaction with Sumitomo pursuant to which Sumitomo terminated its existing options to acquire RSL's equity interests in certain of its subsidiaries. See Note 19, "Subsequent Events" for additional information.

Note 6—Discontinued Operations

As a result of the Sumitomo Transaction Agreement, see Note 5, "Sumitomo Transaction Agreement," the financial results of the Sumitovant Vants are presented as "Income from discontinued operations, net of tax" in the accompanying consolidated statements of operations for the year ended March 31, 2020. There were no operating results from discontinued operations for the year ended March 31, 2021.

The following table presents components of discontinued operations included in “Income from discontinued operations, net of tax” for the year ended March 31, 2020 (in thousands).

	Year Ended March 31, 2020
Operating expenses:	
Research and development	$ 265,452
General and administrative	119,885
Total operating expenses	385,337
Loss from operations	(385,337)
Gain on sale of business	(1,985,949)
Interest income	(2,305)
Interest expense(1)	13,733
Other expense	8,866
Income from discontinued operations before income taxes	1,580,318
Income tax expense	1,892
Income from discontinued operations, net of tax	$ 1,578,426
Loss from discontinued operations before income taxes attributable to noncontrolling interests	$ (141,783)
Income from discontinued operations before income taxes attributable to Roivant Sciences Ltd.	1,722,101
Income from discontinued operations before income taxes	$ 1,580,318

(1) Interest expense consists of interest payments related to outstanding debt held by Myovant and Urovant as well as the associated non-cash amortization of debt discounts and issuance costs.

In the accompanying consolidated statements of cash flows, the cash flows from discontinued operations are not separately classified. The significant cash flow items from discontinued operations were as follows (in thousands):

	Year Ended March 31, 2020
Gain on sale of business	$ (1,985,949)
Share-based compensation	$ 54,821
Acquired in-process research and development	$ 16,405

Note 7—Balance Sheet Components

(A) Other Current Assets

Other current assets at March 31, 2021 and 2020 consisted of the following (in thousands):

	March 31, 2021	March 31, 2020
Prepaid expenses	$ 39,544	$ 16,344
Receivables for value added tax (VAT) paid	807	5,978
Note receivable	—	5,000
Trade receivables, net	11,222	3,669
Income tax receivable	1,803	632
Other	874	2,140
Total other current assets	$ 54,250	$ 33,763

(B) Accrued Expenses

Accrued expenses at March 31, 2021 and 2020 consisted of the following (in thousands):

	March 31, 2021	March 31, 2020
Research and development expenses	$ 20,755	$ 21,607
Compensation-related expenses	38,552	29,113
Professional services expenses	10,267	5,135
Other general and administrative expenses	7,362	12,766
Total accrued expenses	$ 76,936	$ 68,621

(C) Other Current Liabilities

Other current liabilities at March 31, 2021 and 2020 consisted of the following (in thousands):

	March 31, 2021	March 31, 2020
Deferred revenue	$ 5,918	$ 3,621
Income tax payable	207	1,497
Other	3,037	234
Total other current liabilities	$ 9,162	$ 5,352

Note 8—Long-Term Debt

(A) Long-Term Debt

Long-term debt, net consists of the following (in thousands):

	March 31, 2021	March 31, 2020
Principal amount	$ 171,490	$ 110,490
Less: unamortized debt discount and issuance costs	(1,210)	(1,898)
Total debt, net	170,280	108,592
Less: current portion	—	—
Total long-term debt, net	$ 170,280	$ 108,592

Dermavant

In May 2019, Dermavant and certain of its subsidiaries entered into a loan and security agreement (the “Hercules Loan Agreement”) with Hercules Capital, Inc. (“Hercules”), pursuant to which Dermavant borrowed an aggregate of $20.0 million which bears interest at a variable per annum rate at the greater of (i) 9.95% or (ii) the prime rate plus 4.45%. Dermavant is obligated to pay an end of term charge of $1.4 million with the debt maturing 36 months from closing, subject to extension with the achievement of a clinical milestone. Dermavant is obligated to make monthly payments of accrued interest for the first 15 months after closing (the “Interest-only Period”), followed by monthly installments of principal and interest through the maturity date, subject to extension upon certain milestone achievements. In January 2020, the Interest-only Period was extended through June 2021 upon Dermavant’s receipt of net proceeds from equity or debt financings, capital contributions, and proceeds from business development or similar transaction of at least $110.0 million. In July 2020, the clinical milestone was achieved and the term loan maturity was extended to June 1, 2023 and the Interest-only Period was further extended through December 2021. As of March 31, 2021 and March 31, 2020, an aggregate principal amount of $20.0 million and end of term charge of $1.4 million remained outstanding. In May 2021, Dermavant

repaid all amounts outstanding under the Hercules Loan Agreement using the proceeds from the $40.0 million Credit Facility entered into by Dermavant and certain of its subsidiaries in May 2021. Refer to Note 19, “Subsequent Events” for additional detail.

In connection with Dermavant’s acquisition of tapinarof from GSK, Dermavant and NovaQuest Co-Investment Fund VIII, L.P. (“NovaQuest”) entered into a funding agreement (the “NovaQuest Agreement”). Pursuant to the NovaQuest Agreement, Dermavant borrowed $100.0 million in August 2018 and $17.5 million in October 2018 in exchange for an obligation to make certain variable future payments calculated as a function of the achievement of regulatory and commercial milestones or events of termination. The aggregate maximum amount of regulatory milestone payments that Dermavant could be required to make under the NovaQuest Agreement is $440.6 million, and the maximum aggregate amount of commercial milestone payments is $141.0 million. In some circumstances, Dermavant may be able to offset certain of the regulatory milestone payments with up to $88.1 million of the commercial milestone payments. At issuance, the Company concluded that certain features of the long-term debt would be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, the Company has elected the fair value option for this financial instrument and will record the changes in the fair value within the statements of operations at the end of each reporting period. Direct costs and fees related to the debt issued under the NovaQuest Agreement were recognized in earnings. As of March 31, 2021 and 2020, the fair value of the debt was $150.1 million and $89.1 million, respectively. Refer to Note 15, “Fair Value Measurements” for additional details regarding the fair value measurement.

(B) Debt Maturities

Annual maturities, including the end of term charge, of debt outstanding as of March 31, 2021 are as follows (in thousands). Long-term debt held by Dermavant for which the fair value option has been elected is excluded from the below as the repayment terms are variable.

Years Ending March 31,	
2022	$ 3,129
2023	13,306
2024	4,955
2025	—
2026	—
Thereafter	—
Total	$ 21,390

Note 9—Related Party Transactions

Transition Services Agreement and Strategic Cooperation Agreement with Sumitomo

Concurrently with the Sumitomo Transaction Agreement, (i) RSL, Sumitomo and Sumitovant entered into a transition services agreement, whereby each of the parties thereto agreed to provide certain services to one another at cost for a period of time following the Sumitomo Closing Date and (ii) RSL and Sumitomo entered into a strategic cooperation agreement relating to certain ongoing technology-related collaborations between the parties. Pursuant to the terms of the transition services agreement and strategic cooperation agreement, RSL billed Sumitovant $1.4 million and $0.2 million, net of amounts billed by Sumitovant to RSL, respectively, during the years ended March 31, 2021 and 2020 for costs incurred on behalf of Sumitovant, which were recorded as offsets to the general and administrative expenses initially charged. Additionally, during the years ended March 31, 2021 and 2020, the Company paid Sumitomo a $1.0 million access fee pursuant to the strategic cooperation agreement.

Note 10—Shareholders' Equity and Redeemable Noncontrolling Interest

(A) Sumitomo Transaction Agreement and Roivant Equity Repurchase

In December 2019, RSL and Sumitomo completed the transactions contemplated by the Sumitomo Transaction Agreement; see Note 5, "Sumitomo Transaction Agreement." Pursuant to the Sumitomo Transaction Agreement, RSL issued 78,867,360 common shares to Sumitomo at closing at a price per share of $12.68 for allocated net proceeds of approximately $999.2 million, after offering expenses incurred. In connection with the Sumitomo Closing Date, RSL's board of directors approved a repurchase of up to $1.0 billion of the Company's equity securities using the proceeds received from Sumitomo.

In February 2020, the Company launched one-time offers to purchase up to $1.0 billion of issued and outstanding equity securities of the Company (the "Roivant Equity Repurchase"). The offers included (i) an offer to repurchase up to approximately 11.23% of the common stock held by each holder (and its affiliates) of the Company's common stock as of December 26, 2019, at a price per share of $12.68 representing fair value of the common stock, (ii) an offer to purchase vested stock options whose fair market value (as determined as of December 27, 2019) was less than or equal to the fair market value of approximately 11.23% of the earliest-granted of such holder's outstanding vested and unvested stock options, at a purchase price equal to such vested option's fair market value, and (iii) an offer to holders of performance restricted stock units ("pRSUs") to surrender 100% of their existing pRSUs in exchange for newly issued performance stock options and capped value appreciation rights. The offer to the holders of pRSUs included an offer by the Company to immediately purchase approximately 11.23% of the newly issued performance stock options and capped value appreciation rights for cash. The Company additionally entered into an agreement with the Company's Founder to repurchase a portion of his common stock held and exchange his pRSUs for performance stock options and capped value appreciation rights. A summary of payments made during the year ended March 31, 2020 relating to the purchase of equity securities by the Company is as follows (in thousands):

	Cash Payment
Common stock	$ 950,722
Other equity instruments	39,292
Total cash paid	$ 990,014

(B) Consolidated Vant Equity Transactions

Cytovant Sciences HK Limited

In March 2020, Cytovant Sciences HK Limited ("Cytovant"), a subsidiary of the Company, issued and sold 20,085,301 Series A-1 preference shares at a purchase price of $1.17 per share to third party investors for aggregate net proceeds of $22.5 million after deducting offering costs. The preferred stock is convertible into ordinary shares of Cytovant at any time at the option of the investor, or automatically upon a qualified initial public offering ("Qualified IPO") as defined in the subscription agreement. If a Qualified IPO is not completed within five years of the initial investment, Series A preference shareholders can force a sale or liquidation of Cytovant. The Series A-1 preference shares are classified as redeemable noncontrolling interest in the accompanying consolidated balance sheets and consolidated statements of shareholders' equity and redeemable noncontrolling interest as the Company can be obligated to repurchase the Series A-1 preference shares upon the occurrence of certain contingent events outside the Company's control. No dividends shall accrue or be payable on the convertible and redeemable preferred stock unless otherwise determined by the board of directors of Cytovant. The Company did not accrete changes in the redemption value as of March 31, 2021 as the Company considers the events leading to a redemption of the convertible and redeemable preferred stock as not probable.

Immunovant

In September 2019, Immunovant Sciences Ltd. ("ISL") entered into a share exchange agreement (the "Share Exchange Agreement") with Health Sciences Acquisitions Corporation ("HSAC"), and in December 2019, ISL

and HSAC completed the transactions contemplated by the Share Exchange Agreement (the "Business Combination"). At closing, HSAC acquired 100% of the issued and outstanding common shares of ISL in exchange for 42,080,376 shares of HSAC's common stock issued to HSAC, ISL, and the shareholders of ISL (together, the "Sellers") and 10,000 shares of HSAC Series A preferred shares issued to RSL. Additionally, as part of its initial public offering in May 2019, HSAC issued common stock warrants, which are classified in equity. Upon completion of the Business Combination, 11,500,000 warrants were outstanding for the purchase of one-half of one share of common stock (an aggregate of 5,750,000 common shares) at a price of $11.50 per whole share. Upon closing, ISL became a wholly owned subsidiary of HSAC and HSAC was renamed "Immunovant, Inc." The Business Combination was accounted for as a reverse recapitalization and HSAC was treated as the "acquired" company for accounting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of ISL issuing equity for the net assets of HSAC, accompanied by a recapitalization. Immunovant, Inc. received $111.0 million in cash as a result of the Business Combination, consisting of the funds held in HSAC's trust account. The proceeds included $5.1 million related to common shares purchased by RSL.

The sellers were entitled to receive an additional 20,000,000 shares of Immunovant, Inc.'s common stock (the "Earnout Shares") if the volume-weighted average price of Immunovant, Inc.'s shares equaled or exceeded the following prices for any 20 trading days within any 30 trading-day period (the "Trading Period") following the closing of the Business Combination:

(i) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least $17.50 per share; and

(ii) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least $31.50 per share.

In May 2020 and September 2020, Immunovant, Inc. achieved the first earnout milestone and second earnout milestone, respectively, under the Share Exchange Agreement and, as a result, all of the 20,000,000 earnout shares of Immunovant, Inc.'s common stock were issued to former stockholders of ISL, including 17,547,938 shares of common stock issued to RSL. In addition, upon the achievement of the first earnout milestone and second earnout milestone and pursuant to the restricted stock agreement entered into between HSAC and Health Sciences Holdings, LLC (the "Sponsor"), all of the 1,800,000 shares of the Sponsor's restricted shares vested and are no longer subject to forfeiture.

Immediately prior to the closing of the Business Combination, as described above, ISL's convertible promissory notes were automatically converted into an aggregate of 7,156,495 common shares of ISL, which were then exchanged for an aggregate of 3,499,995 shares of Immunovant, Inc. common stock upon the closing of transactions contemplated by the Share Exchange Agreement. The conversion of ISL's convertible promissory notes resulted in an increase to equity by $35.6 million, the carrying amount of the convertible promissory notes. The conversion included a convertible promissory note held by RSL for $2.5 million.

In April 2020, Immunovant, Inc. completed an underwritten public offering of 9,613,365 shares of its common stock, including 1,034,483 shares of common stock purchased by RSL, at a price of $14.50 per share for net proceeds to Immunovant, Inc. of approximately $131.0 million, after deducting underwriting discounts and commissions and offering expenses. The proceeds included $15.0 million received from RSL.

In May 2020, Immunovant, Inc.'s 11,500,000 outstanding warrants became exercisable for an aggregate of 5,750,000 shares of Immunovant, Inc.'s common stock at a price of $11.50 per share. An aggregate of 11,438,290 outstanding warrants were exercised for an aggregate of 5,719,145 shares of Immunovant, Inc.'s common stock at a price of $11.50 per share, for net proceeds of approximately $65.8 million. The remaining 61,710 warrants were cancelled.

In September 2020, Immunovant, Inc. completed an underwritten public offering of 6,060,606 shares of its common stock, including 380,000 shares of common stock purchased by RSL, at a price of $33.00 per share for

net proceeds to Immunovant, Inc. of approximately $188.1 million, after deducting underwriting discounts and commissions and offering expenses. The proceeds included $12.5 million received from RSL.

Sinovant

Sinovant, a subsidiary of the Company, previously issued and sold preferred stock convertible into ordinary shares of Sinovant at any time at the option of the investors or automatically upon a qualified initial public offering ("Qualified IPO") as defined in the subscription agreement relating to the sale of the preferred stock. The convertible preferred stock was redeemable at the option of the investor if a Qualified IPO was not completed within five years of the initial investment and was payable in cash equal to the investment amount plus an annualized return of 12%. As such events are not within the control of the Company, the preferred stock was previously classified as redeemable noncontrolling interest in the accompanying consolidated balance sheets and consolidated statements of shareholders' equity and redeemable noncontrolling interest. No dividends accrued or were payable on the convertible preferred stock. In January 2020, Sinovant's parent company, Roivant China Holdings Ltd. ("RCHL"), purchased all preferred stock of Sinovant held by third parties at a purchase price of $12.26 per preferred share for an aggregate purchase price of $132.9 million. Consideration paid in excess of the carrying value for the repurchase of redeemable noncontrolling interest of $77.8 million is considered a deemed dividend. See Note 18, "Earnings per Common Share" for resulting impact to earnings per share.

Note 11—Share-Based Compensation

(A) RSL 2015 Equity Incentive Plan

As of March 31, 2021, 66,717,360 of the Company's common shares (the "Share Reserve") are reserved for issuance under the RSL Amended and Restated 2015 Equity Incentive Plan (the "RSL 2015 EIP"). At March 31, 2021, a total of 30,129,783 common shares are available for future grants under the RSL 2015 EIP. The Company's employees, directors, and consultants are eligible to receive nonstatutory and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards under the RSL 2015 EIP.

As of March 31, 2021, an aggregate of 77,714,699 of the Company's common shares (the "Special Reserve") were reserved for the granting under RSL 2015 EIP of performance stock options ("Performance Options") and capped value appreciation rights ("CVARs") to the Company's employees, directors and consultants. At March 31, 2021, there are no common shares available for future grant under the Special Reserve.

Stock Options

For the years ended March 31, 2021 and 2020, the Company recorded share-based compensation expense related to stock options issued under the RSL 2015 EIP to employees and directors of approximately $32.3 million and $31.8 million, respectively, and was included in research and development and general and administrative expenses in the accompanying consolidated statements of operations.

At March 31, 2021, total unrecognized compensation expense related to non-vested stock options was approximately $70.8 million and is expected to be recognized over the remaining weighted-average service period of 2.96 years.

The Company estimated the fair value of each stock option on the date of grant using the Black-Scholes closed form option-pricing model applying the weighted average assumptions in the following table.

	Years Ended March 31,	
Assumptions	**2021**	**2020**
Expected stock price volatility	74.84%	66.47%
Expected risk free interest rate	0.43%	2.27%
Expected term, in years	6.25	6.72
Expected dividend yield	— %	— %

A summary of stock option activity and data under the RSL 2015 EIP for the year ended March 31, 2021 is as follows:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life
Stock options outstanding at March 31, 2020	23,926,758	$ 8.38	$ 5.65	7.93
Granted	4,338,396	$ 13.23	$ 8.67	
Forfeited/Canceled	(790,212)	$ 10.21	$ 6.78	
Stock options outstanding at March 31, 2021	27,474,942	$ 9.10	$ 6.12	7.26
Stock options exercisable at March 31, 2021	16,193,146	$ 7.35	$ 5.11	6.49

At March 31, 2021 and 2020, there were 16,193,146 and 12,067,511 vested stock options, respectively. Additional information regarding stock options is set forth below (in thousands, except per share data).

	Years Ended March 31,	
	2021	**2020**
Grant date fair value of stock options vested	$ 25,711	$ 33,789
Weighted-average grant date fair value per share of stock options granted	$ 8.67	$ 7.05

Restricted Stock Units

Restricted stock units will vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date. Restricted stock units expire eight years after the date of grant. During the year ended March 31, 2021, the Company recorded no share-based compensation expense related to these restricted stock units as the liquidity event requirement had not been met and was deemed not probable of being met. At March 31, 2021, there was approximately $83.8 million of unrecognized compensation expense related to non-vested restricted stock units. The Company will recognize the expense upon achievement of both the time-based service requirement and liquidity requirements through the requisite service period.

A summary of restricted stock units under the RSL 2015 EIP is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2020	2,949,911	$ 11.11
Granted	4,255,277	$ 13.39
Forfeited	(496,389)	$ 12.43
Non-vested balance at March 31, 2021	6,708,799	$ 12.48

Performance Options

Performance Options will vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date of March 31, 2026. During the year ended March 31, 2021, the Company recorded no share-based compensation expense related to these Performance Options as the liquidity event requirement had not been met and was deemed not probable of being met. At March 31, 2021, there was approximately $337.8 million of unrecognized compensation expense related to non-vested
Performance Options. The Company will recognize the expense upon achievement of both the time-based service requirement and liquidity requirements through the requisite service period.

The Company estimated the fair value of each Performance Option on the date of grant using the Black-Scholes closed form option-pricing model applying the weighted average assumptions in the following table.

Assumptions	Year Ended March 31, 2020
Expected stock price volatility	73.60%
Expected risk free interest rate	0.62%
Expected term	6 years
Expected dividend yield	— %

A summary of Performance Option activity and data under the RSL 2015 EIP for the year ended March 31, 2021 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life
Performance Options outstanding at March 31, 2020	42,485,108	$ 13.32	$ 8.13	6.00
Granted	—	$ —	$ —	
Forfeited	(272,742)	$ 15.85	$ 7.58	
Performance Options outstanding at March 31, 2021	42,212,366	$ 13.30	$ 8.01	5.00

No Performance Options were exercisable at March 31, 2021.

CVARs

CVARs will vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date of March 31, 2026. At settlement, each CVAR pays in common shares the excess of (a) the lesser of (i) the fair market value of a common share as of the settlement date or (ii) the cap of $12.68, over (b) the hurdle price of either $6.40 or $11.50, as applicable to each grant. During the year ended March 31, 2021, the Company recorded no share-based compensation expense related to these CVARs as the liquidity event requirement had not been met and was deemed not probable of being met. At March 31, 2021, there was approximately $23.0 million of unrecognized compensation expense related to non-vested CVARs. The Company will recognize the expense upon achievement of both the time-based service requirement and liquidity requirements through the requisite service period.

A summary of CVARs under the RSL 2015 EIP is as follows:

	Number of CVARs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2020	32,447,626	$ 0.72
Granted	—	$ —
Forfeited	—	$ —
Non-vested balance at March 31, 2021	32,447,626	$ 0.72

(B) RSL 2015 Restricted Stock Unit Plan

Under the Amended and Restated RSL 2015 Restricted Stock Unit Plan (the "pRSU Plan"), as of March 31, 2021, there are 585,229 of the Company's common shares reserved for issuance in connection with pRSUs that may be granted to employees, officers, directors and consultants of the Company under the pRSU Plan. The pRSUs expire eight years after the date of grant. At March 31, 2021, none of the Company's common shares were reserved for future grants under this plan.

As part of the Roivant Equity Repurchase, 49,875,513 existing pRSUs were surrendered and exchanged for newly issued Performance Options and CVARs issued under an amended and restated RSL 2015 EIP (see above), of which approximately 11.23% were then immediately purchased by the Company, during the year ended March 31, 2020. Refer to Note 10, "Shareholders' Equity and Redeemable Noncontrolling Interest" for additional detail regarding the Roivant Equity Repurchase.

A summary of pRSU activity under the pRSU Plan is as follows:

	Number of pRSUs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2020	780,831	$ 4.76
Granted	—	$ —
Forfeited	(195,602)	$ 4.76
Non-vested balance at March 31, 2021	585,229	$ 4.76

These pRSUs will vest to the extent certain performance criteria are achieved and certain liquidity conditions are satisfied within specified years of the grant date, provided that the recipient has provided continued service through such date. As of March 31, 2021, the performance conditions had not been met and were deemed not probable of being met. During the year ended March 31, 2021, the Company recorded no share-based compensation expense related to these pRSUs. During the year ended March 31, 2020, the Company recorded $12.3 million of share-based compensation expense relating to cash payments made for the purchase of a portion of the Performance Options and CVARs issued in replacement of pRSUs. At March 31, 2021, there was approximately $2.8 million of unrecognized compensation expense related to non-vested pRSUs. The Company will recognize the expense upon achievement of the performance and liquidity conditions through the requisite service period.

(C) RSL Restricted Common Stock

A summary of RSL restricted common stock activity as of March 31, 2021 is as follows:

	Number of Restricted Common Stock	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2020	—	$ —
Granted	1,720,090	$ 13.16
Vested	—	$ —
Forfeited	—	$ —
Non-vested balance at March 31, 2021	1,720,090	$ 13.16

For the year ended March 31, 2021, the Company recorded share-based compensation expense of $0.1 million in relation to the RSL restricted common stock. At March 31, 2021, total unrecognized compensation expense related to non-vested restricted common stock was approximately $6.9 million and is expected to be recognized over the remaining weighted-average service period of 3.39 years. $15.6 million of the fair value associated with these restricted common stock was attributed to precombination service. Refer to Note 4, “Asset Acquisitions and License Agreements.”

(D) Subsidiary Equity Incentive Plans

Certain wholly owned and majority-owned or controlled subsidiaries of RSL adopt their own equity incentive plan (“EIP”). Each EIP is generally structured so that the applicable subsidiary, and its affiliates’ employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted stock unit awards, and other share awards under their respective EIP. Standard option grants have time-based vesting requirements, generally vesting over a period of four years with a contractual term of ten years. Such time-based stock options use the Black-Scholes option pricing model. The grant date fair value of awards subject to market conditions is estimated using a Monte Carlo valuation model. For the years ended March 31, 2021 and 2020, the Company recorded share-based compensation expense of $29.1 million and $22.1 million, respectively, in relation to subsidiary EIPs.

(E) Share-Based Compensation Expense

Share-based compensation expense from continuing operations was as follows (in thousands):

	Years Ended March 31,	
	2021	2020
Share-based compensation expense recognized as:		
R&D expenses	$ 22,637	$ 7,738
G&A expenses	62,321	60,013
Total	$ 84,958	$ 67,751

The classification of share-based compensation expense between R&D and G&A expenses in the accompanying consolidated statements of operations is consistent with the classification of grantee’s salary expense.

Note 12—Income Taxes

The loss before income taxes and the related expense/(benefit) are as follows (in thousands):

	Years Ended March 31,	
	2021	2020
Loss before income taxes:		
United States	$(212,921)	$ (69,264)
Switzerland	(424,494)	(355,422)
Bermuda	(227,471)	(105,604)
Other(1)	(33,661)	(30,696)
Total loss before income taxes	$(898,547)	$(560,986)

(1) Primarily Greater China and United Kingdom activity

	Years Ended March 31,	
	2021	2020
Current taxes:		
United States	$ 1,365	$ 6,327
Switzerland	—	—
Bermuda	—	—
Other(1)	321	797
Total current tax expense	$ 1,686	$ 7,124
Deferred taxes:		
United States	$ —	$ —
Switzerland	—	—
Bermuda	—	—
Other(1)	—	—
Total deferred tax benefit	$ —	$ —
Total income tax expense	$ 1,686	$ 7,124

(1) Primarily Greater China, United States state and local and United Kingdom activity

A reconciliation of income tax provision/(benefit) computed at the Bermuda statutory rate to income tax expense reflected in the consolidated financial statements is as follows (in thousands, except percentages):

	Year Ended March 31, 2021		Year Ended March 31, 2020	
Income tax benefit at Bermuda statutory rate	$ —	— %	$ —	— %
Foreign rate differential(1)	(150,778)	16.78%	(74,922)	13.36%
Permanent disallowed IPR&D	111,432	(12.40)%	—	— %
Nondeductible changes in the fair value of investments and loss from equity method investment	(22,472)	2.50%	20,840	(3.72)%
Nontaxable (loss) gain on deconsolidation of business	(16,438)	1.83%	29,041	(5.18)%
Permanent adjustments	2,923	(0.33)%	(20,395)	3.64%
R&D tax credits	(10,555)	1.17%	(5,990)	1.07%
Rate changes	2,443	(0.27)%	(29,238)	5.21%
Valuation allowance	85,046	(9.46)%	87,677	(15.63)%
Other	85	(0.01)%	111	(0.02)%
Total income tax expense	$ 1,686	(0.19)%	$ 7,124	(1.27)%

(1) Primarily related to operations in Switzerland, the United Kingdom, and other jurisdictions with statutory tax rates different than the Bermuda rate.

The Company's effective tax rates were (0.19)% and (1.27)% for the years ended March 31, 2021 and 2020, respectively, driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2021 and 2020 are as follows (in thousands):

	March 31, 2021	March 31, 2020
Deferred tax assets		
Research tax credits	$ 19,063	$ 6,303
Intangible assets	50,564	43,626
Net operating loss	202,906	116,619
Share-based compensation	26,623	18,413
Lease liabilities	16,638	17,194
Other	7,303	7,060
Subtotal	323,097	209,215
Valuation allowance	(303,287)	(187,831)
Deferred tax liabilities		
Depreciation	(1,214)	(1,833)
Right-of-use assets	(13,908)	(15,409)
Other	(4,688)	(4,142)
Total deferred tax assets (liabilities)	$ —	$ —

The Company has Federal net operating losses in Switzerland, the United States, the United Kingdom and other jurisdictions in the amount of $1,181.1 million, $122.2 million, $28.6 million, and $75.8 million, respectively. The Switzerland net operating losses will expire in varying amounts between March 31, 2025 and March 31, 2028. The United States net operating losses can be carried forward indefinitely with utilization limited to 80%

of future taxable income for tax years beginning on or after January 1, 2021, while the United Kingdom and other net operating losses can be carried forward indefinitely as well, with an annual limitation on utilization. The Company has generated net operating losses from United States state and local jurisdictions in the amount of $69.7 million which will expire in varying amounts between March 31, 2035 and March 31, 2041. The Company has generated $19.1 million of research tax credit carryforwards primarily in the United States, which will expire in varying amounts between March 31, 2035 and March 31, 2041.

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and record a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of $303.3 million as of March 31, 2021, representing the portion of the deferred tax asset that is not more likely than not to be realized. The amount of the deferred tax asset considered realizable could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. For the period April 1, 2020 through March 31, 2021, the valuation allowance increased by $115.5 million primarily as a result of corresponding increases in our global net operating losses, as well as our Research Tax Credits. For the period April 1, 2019 through March 31, 2020, the valuation allowance decreased by $168.0 million primarily as a result of the Sumitomo Transaction and the deconsolidation of Sio. The Company will continue to assess the realizability of deferred tax assets at each balance sheet date in order to determine the amount, if any, required for a valuation allowance.

There are outside basis differences related to the Company's investment in subsidiaries for which no deferred taxes have been recorded as these would not be subject to tax on repatriation as Bermuda has no tax regime for Bermuda exempted limited companies, and the United Kingdom tax regime relating to company distributions and sales generally provides for exemption from tax for most overseas profits, subject to certain exceptions.

The Company is subject to tax and is required to file United States, United Kingdom, and Switzerland federal income tax returns, as well as income tax returns in various state, local, and foreign jurisdictions. The Company is subject to tax examinations for tax years ended March 31, 2018 and forward in major taxing jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however, the potential tax benefits may impact the results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. There are no unrecognized tax benefits recorded as of March 31, 2021 and 2020.

Note 13—Leases

The Company's operating leases consist primarily of real estate leases, including those entered into by certain wholly owned and majority-owned or controlled subsidiaries of RSL. The Company determines if an agreement is or contains a lease at inception. Leases with an initial term of 12 months or less are not recorded on the balance sheet. For real estate leases, the Company elected the expedient to account for lease and non-lease components as a single component.

Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are based on the estimated present value of fixed lease payments over the expected lease term and are recognized at the lease commencement date.

As most of the Company's leases do not provide an implicit rate, the Company uses an estimated incremental borrowing rate in determining the present value of fixed lease payments based on information available at the lease commencement date. The Company's incremental borrowing rates are determined based on the term of the lease, the economic environment of the lease, and the effect of collateralization. Certain leases include one or

more renewal options, generally for the same period as the initial term of the lease. The exercise of lease renewal options is generally at the Company's sole discretion and, as such, the Company typically determines that exercise of these renewal options is not reasonably certain. As a result, the Company does not include the renewal option period in the expected lease term and the associated lease payments are not included in the measurement of the ROU asset and lease liability. Certain leases also contain termination options with an associated penalty. Generally, the Company is reasonably certain not to exercise these options and as such, they are not included in the determination of the expected lease term. The Company recognizes operating lease expense on a straight-line basis over the lease term.

Leases generally provide for payments of nonlease components, such as common area maintenance, real estate taxes and other costs associated with the leased property. For lease agreements entered into or modified after April 1, 2019, the Company accounts for lease components and nonlease components together as a single lease component and, as such, includes fixed payments of nonlease components in the measurement of the ROU assets and lease liabilities. Variable lease payments, such as periodic adjustments for inflation, reimbursement of real estate taxes, any variable common area maintenance and any other variable costs associated with the leased property are expensed as incurred as variable lease costs and are not recorded on the balance sheet.

The Company's lease agreements do not contain any material residual value guarantees or material restrictions or covenants.

The components of operating lease expense for the Company were as follows (in thousands):

	Years Ended March 31,	
	2021	2020
Operating lease cost	$ 11,931	$ 11,515
Short-term lease cost	237	872
Variable lease cost	704	379
Total operating lease cost	$ 12,872	$ 12,766

Information related to the Company's operating lease ROU assets and operating lease liabilities was as follows (in thousands, except periods and percentages):

	During the Year Ended March 31,	
	2021	2020
Cash paid for operating lease liabilities	$8,830	$ 8,108
Operating lease ROU assets obtained in exchange for operating lease liabilities	$5,491	$56,025

	March 31, 2021	March 31, 2020
Weighted average remaining lease term (in years)	9.6	10.2
Weighted average discount rate	7.1%	7.1%

As of March 31, 2021, maturities of operating lease liabilities were as follows (in thousands):

Years Ending March 31,	
2022	$ 13,386
2023	11,814
2024	11,718
2025	9,734
2026	8,617
Thereafter	51,674
Total lease payments	106,943
Less: present value adjustment	(29,348)
Less: tenant improvement allowance	(2,898)
Total	$ 74,697

Note 14—Commitments and Contingencies

(A) Significant Agreements

The Company, primarily through its subsidiaries has entered into commitments under various asset acquisition and license agreements including those described in Note 4, “Asset Acquisitions and License Agreements.” Additionally, the Company through its subsidiaries enters into agreements with contract service providers to assist in the performance of its R&D activities. Expenditures to contract research organizations and contract manufacturing organizations represent significant costs in the clinical development of its product candidates. Subject to required notice periods and certain obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(B) Loss Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated, and if the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation or claim, including an estimable range, if possible. The Company is currently not involved in any legal proceedings with a probable and estimable material loss.

(C) Intellectual Property Agreements

As of March 31, 2021, the Company did not have any ongoing material financial commitments, other than pursuant to various asset acquisition and license agreements including those described in Note 4, “Asset Acquisitions and License Agreements.”

(D) COVID-19 Pandemic

The Company has been actively monitoring the impact of the COVID-19 pandemic on its employees and business. Based on guidance issued by federal, state and local authorities, the Company transitioned to a remote work model for its employees in March 2020 and its workforce continues to primarily work remotely.

The COVID-19 pandemic has had a variable impact on clinical trials by disrupting certain study sites. In the conduct of business activities, the Company continues to take actions designed to protect the safety and well-

being of its patients and employees. Although some of the Company's clinical development timelines have been impacted by delays related to the COVID-19 pandemic, the Company has not experienced material financial impacts on its business and operations as a result of the COVID-19 pandemic. However, the impact on the Company's future results will largely depend on future developments related to COVID-19, which are highly uncertain and cannot be predicted with confidence, such as the emergence of new variants, the ultimate duration and spread of the outbreak, the continuing impact of the COVID-19 pandemic on financial markets and the global economy, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain, treat, and prevent the disease, including the availability and effectiveness of vaccines.

Note 15—Fair Value Measurements

Recurring Fair Value Measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2021 and 2020, by level, within the fair value hierarchy (in thousands):

	As of March 31, 2021				As of March 31, 2020			
	Level 1	Level 2	Level 3	Balance as of March 31, 2021	Level 1	Level 2	Level 3	Balance as of March 31, 2020
Assets:								
Money market funds	$ 1,420,597	$ —	$ —	$ 1,420,597	$ 1,874,662	$ —	$ —	$ 1,874,662
Investment in Sio common shares	48,487	—	—	48,487	45,329	—	—	45,329
Investment in Arbutus common shares	53,325	—	—	53,325	16,174	—	—	16,174
Investment in Arbutus convertible preferred shares	—	76,037	—	76,037	—	23,062	—	23,062
Other investments	11,129	—	—	11,129	8,880	—	—	8,880
Total assets at fair value	$ 1,533,538	$ 76,037	$ —	$ 1,609,575	$ 1,945,045	$ 23,062	$ —	$ 1,968,107
Liabilities:								
Debt held by Dermavant with NovaQuest	$ —	$ —	$ 150,100	$ 150,100	$ —	$ —	$ 89,100	$ 89,100
Liability instruments measured at fair value	—	—	67,893	67,893	—	—	102,373	102,373
Total liabilities at fair value	$ —	$ —	$ 217,993	$ 217,993	$ —	$ —	$ 191,473	$ 191,473

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the years ended March 31, 2021 and 2020.

Level 3 Disclosures

The Company measures its Level 3 liabilities, including debt issued by Dermavant to NovaQuest and the Sumitomo Options, at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the Level 3 liabilities uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value related to updated assumptions and estimates are recorded within the statements of operations at the end of each reporting period.

The fair value of Level 3 liabilities may change significantly as additional data are obtained, impacting the Company's assumptions regarding probabilities of potential scenarios used to estimate fair value. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The changes in fair value of the Level 3 liabilities during the years ended March 31, 2021 and 2020 were as follows (in thousands):

Balance at March 31, 2019	$103,628
Issuance of liability instruments measured at fair value	101,567
Changes in fair value of debt and liability instruments, included in net loss	(13,722)
Balance at March 31, 2020	191,473
Changes in fair value of debt and liability instruments, included in net loss	29,845
Liability instruments disposed due to deconsolidation of subsidiary	(3,325)
Balance at March 31, 2021	$217,993

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of March 31, 2021 and 2020 represents the fair value of amounts payable to NovaQuest using a Monte Carlo simulation model under the income approach determined by using probability assessments of the expected future payments through 2032 and applying discount rates ranging from 6% to 17%. The future payments are based on significant inputs that are not observable in the market which are subject to remeasurement at each reporting date. The estimates of fair value may not be indicative of the amounts that could ultimately be paid by Dermavant to NovaQuest.

Sumitomo Options

The fair value of the options to acquire the Company's interest in Dermavant, Genevant, Lysovant, Metavant, Cytovant Parent, and Sinovant (collectively, the "Option Vants") granted to Sumitomo under the Sumitomo Transaction Agreement as of March 31, 2021 and 2020 was calculated using significant unobservable inputs including the following:

	Range or Point Estimate Used	
Input	As of March 31, 2021	As of March 31, 2020
Time to expiration (in years)	3.59	0.49 - 4.59
Risk-free rate	0.52%	0.15% - 0.35%
Volatility	89.0% - 95.0%	91.0% - 110.0%

As of March 31, 2021 and 2020, the fair value of the Sumitomo Options was $62.4 million and $95.9 million, respectively. Sumitomo Options are included in "Liability instruments measured at fair value" in the accompanying consolidated balance sheets.

In June 2021, the Company completed a transaction with Sumitomo pursuant to which Sumitomo terminated all of its existing options to acquire the Company's equity interests in certain subsidiaries. See Note 19, "Subsequent Events" for additional information.

Note 16—Defined Contribution Plan

The Company and certain of its subsidiaries sponsor defined contribution plans pursuant to Section 401(k) of the U.S. Internal Revenue Code. Employee contributions are voluntary and subject to the maximum allowable under federal tax regulations. For the years ended March 31, 2021 and 2020, the Company recorded total expense for employer matching contributions of $1.7 million and $1.7 million, respectively.

Note 17—Other Expense, Net

Other expense, net from continuing operations was as follows (in thousands):

	Years Ended March 31,	
	2021	2020
Loss from equity method investment	$ 3,750	$ 21,386
Interest income	(1,418)	(17,990)
Interest expense	2,809	7,683
Other expense	3,560	2,543
Total	$ 8,701	$ 13,622

Note 18—Earnings per Common Share

The computations of the numerator to derive the basic and diluted earnings per share amounts presented on the face of the accompanying consolidated statements of operations are as follows (in thousands):

	Years Ended March 31,	
	2021	2020
Loss from continuing operations, net of tax	$ (900,233)	$ (568,110)
Net loss from continuing operations, net of tax, attributable to noncontrolling interest	(90,999)	(48,716)
Loss from continuing operations, net of tax, attributable to Roivant Sciences Ltd.	**(809,234)**	**(519,394)**
Deemed dividend on repurchase of redeemable noncontrolling interest relating to subsidiary convertible and redeemable preferred stock(1)	—	(77,777)
Basic and diluted loss from continuing operations, net of tax, attributable to Roivant Sciences Ltd.	**$ (809,234)**	**$ (597,171)**
Income from discontinued operations, net of tax	$ —	$ 1,578,426
Net loss from discontinued operations, net of tax, attributable to noncontrolling interest	—	(141,477)
Net income from discontinued operations, net of tax, attributable to Roivant Sciences Ltd.	**$ —**	**$ 1,719,903**
Basic and diluted income from discontinued operations, net of tax	$ —	$ 1,719,903
Basic and diluted net (loss) income attributable to Roivant Sciences	**$ (809,234)**	**$ 1,122,732**

(1) Consideration paid in excess of carrying value for the repurchase of redeemable noncontrolling interest relating to subsidiary convertible and redeemable preferred stock of $77.8 million is considered a deemed dividend and, for purposes of calculating net loss per share, increases the loss from continuing operations, net of tax, attributable to Roivant Sciences Ltd. for the year ended March 31, 2020. See Note 10, “Shareholders’ Equity and Redeemable Noncontrolling Interest.”

Basic net (loss) income per common share is computed by dividing net (loss) income attributable to Roivant Sciences Ltd. by the weighted-average number of common stock outstanding during the period. Diluted net (loss) income per common share is computed by dividing the net income (loss) attributable to Roivant Sciences Ltd. by the diluted weighted-average number of common stock outstanding during the period.

For periods of loss from continuing operations, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common share equivalents is anti-dilutive. All outstanding common stock equivalents have been excluded from the computation of diluted loss per share because their

effect was anti-dilutive due to the loss from continuing operations. Refer to Note 11, “Share-Based Compensation” and Note 5, “Sumitomo Transaction Agreement” for additional detail regarding outstanding common stock equivalents.

Note 19—Subsequent Events

The Company has evaluated subsequent events for appropriate disclosures through June 30, 2021, the date that the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of March 31, 2021 have been incorporated in these financial statements.

Option Vants Transaction

On May 1, 2021, the Company entered into an Asset Purchase Agreement with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (“SPC”) (the “Asset Purchase Agreement”). The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire the Company’s equity interests in the Option Vants; (ii) the Company transferred and assigned to SPC all of its intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively “Greater China”), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) we will receive a $5.0 million cash payment; and (iv) Sumitomo entered into an agreement with the Company to pursue future collaborations with Genevant.

Dermavant

On May 14, 2021, Dermavant entered into a $160.0 million revenue interest purchase and sale agreement (the “RIPSA”) for its investigational product tapinarof with three institutional investors. Under the terms of the RIPSA, the participants purchased a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States in exchange for $160.0 million in committed funding to be paid to Dermavant, subject to approval of tapinarof by the FDA.

Dermavant concurrently entered into a $40.0 million senior secured credit facility (the “Credit Facility”) with one of the institutional investors. The Credit Facility has a five-year maturity and bears an interest rate of 10% per annum. In connection with the funding of the Credit Facility, Dermavant issued to the institutional investor a warrant to purchase 1,199,072 common shares of Dermavant at an exercise price of $0.01 per common share.

The proceeds from the Credit Facility were used to repay all amounts outstanding under the loan and security agreement with Hercules, with the remainder of net proceeds used for working capital and general corporate purposes. The Company reclassified $3.1 million on the consolidated balance sheets as of March 31, 2021 from current to long-term given that Dermavant had the intent and ability to refinance the short-term obligation on a long-term basis after March 31, 2021 and before the financial statements were issued.

Datavant

In June 2021, Datavant and CIOX Health, LLC entered into a definitive agreement to merge the two companies.
The merger closed on July 27, 2021. At closing, Roivant received approximately $320 million in cash.

ROIVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(unaudited, in thousands, except share and per share amounts)

	September 30, 2021	March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 2,497,330	$ 2,055,044
Restricted cash	2,861	77,701
Other current assets	55,563	54,250
Total current assets	2,555,754	2,186,995
Property and equipment, net	16,904	14,749
Operating lease right-of-use assets	63,198	62,279
Restricted cash, net of current portion	8,933	8,931
Investments measured at fair value	436,780	188,978
Long-term investment	—	100,563
Other assets	21,337	27,197
Total assets	$ 3,102,906	$ 2,589,692
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 77,158	$ 20,550
Accrued expenses	104,111	76,936
Operating lease liabilities	11,518	12,313
Deferred consideration liability	100,000	100,000
Other current liabilities	10,657	9,162
Total current liabilities	303,444	218,961
Liability instruments measured at fair value	75,284	67,893
Operating lease liabilities, noncurrent	65,221	62,384
Long-term debt (includes $168,200 and $150,100 accounted for under the fair value option at September 30, 2021 and March 31, 2021, respectively)	199,869	170,280
Other liabilities	8,189	8,169
Total liabilities	652,007	527,687
Commitments and contingencies (Note 12)		
Redeemable noncontrolling interest	22,491	22,491
Shareholders' equity:(1)		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 684,789,169 and 651,576,293 shares issued and outstanding at September 30, 2021 and March 31, 2021, respectively	—	—
Additional paid-in capital	4,245,860	3,814,805
Subscription receivable	—	(100,000)
Accumulated deficit	(2,209,126)	(1,918,462)
Accumulated other comprehensive income	1,281	1,445
Shareholders' equity attributable to Roivant Sciences Ltd.	2,038,015	1,797,788
Noncontrolling interests	390,393	241,726
Total shareholders' equity	2,428,408	2,039,514
Total liabilities, redeemable noncontrolling interest and shareholders' equity	$ 3,102,906	$ 2,589,692

(1) Retroactively restated for the stock subdivision as described in Note 3.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Revenue, net	$ 13,987	$ 1,323	$ 21,722	$ 2,899
Operating expenses:				
Cost of revenues	6,381	715	7,123	895
Research and development	254,259	97,409	332,885	156,143
General and administrative	437,776	59,740	520,530	116,855
Total operating expenses	698,416	157,864	860,538	273,893
Loss from operations	(684,429)	(156,541)	(838,816)	(270,994)
Change in fair value of investments	(32,273)	(84,297)	(23,654)	(125,445)
Gain on sale of investment	(443,754)	—	(443,754)	—
Change in fair value of debt and liability instruments	13,145	10,148	17,730	27,273
Gain on termination of Sumitomo Options	—	—	(66,472)	—
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	(28,848)	—	(115,364)
Other expense (income), net	3,692	(757)	3,558	2,085
Loss before income taxes	(225,239)	(52,787)	(326,224)	(59,543)
Income tax expense	401	711	494	1,932
Net loss	(225,640)	(53,498)	(326,718)	(61,475)
Net loss attributable to noncontrolling interests	(17,159)	(18,100)	(36,054)	(22,834)
Net loss attributable to Roivant Sciences Ltd.	$ (208,481)	$ (35,398)	$ (290,664)	$ (38,641)
Net loss per common share—basic and diluted(1)	$ (0.32)	$ (0.06)	$ (0.45)	$ (0.06)
Weighted average shares outstanding—basic and diluted(1)	650,225,764	628,779,048	650,041,993	628,779,048

(1) Retroactively restated for the stock subdivision as described in Note 3.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited, in thousands)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (225,640)	$ (53,498)	$ (326,718)	$ (61,475)
Other comprehensive income (loss):				
Foreign currency translation adjustment	2,545	(1,034)	106	(1,854)
Total other comprehensive income (loss)	2,545	(1,034)	106	(1,854)
Comprehensive loss	(223,095)	(54,532)	(326,612)	(63,329)
Comprehensive loss attributable to noncontrolling interests	(17,102)	(18,066)	(35,784)	(22,766)
Comprehensive loss attributable to Roivant Sciences Ltd.	$ (205,993)	$ (36,466)	$ (290,828)	$ (40,563)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Shareholders' Equity and Redeemable Noncontrolling Interest
(unaudited, in thousands, except share data)

	Redeemable Noncontrolling Interest	Shareholders' Equity(1)							
		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount						
Balance at March 31, 2021	$ 22,491	651,576,293	$ —	$3,814,805	$ (100,000)	$ 1,445	$(1,918,462)	$ 241,726	$ 2,039,514
Issuance of subsidiary warrants	—	—	—	2,051	—	—	—	24	2,075
Cash contributions to majority-owned subsidiaries	—	—	—	(2,973)	—	—	—	2,973	—
Share-based compensation	—	—	—	11,091	—	—	—	8,178	19,269
Foreign currency translation adjustment	—	—	—	—	—	(2,652)	—	213	(2,439)
Net loss	—	—	—	—	—	—	(82,183)	(18,895)	(101,078)
Balance at June 30, 2021	$ 22,491	651,576,293	$ —	$3,824,974	$ (100,000)	$ (1,207)	$(2,000,645)	$ 234,219	$ 1,957,341
Issuance of the Company's common shares upon closing of Business Combination and PIPE Financing, net of issuance costs	—	32,372,478	—	129,097	—	—	—	—	129,097
Issuance of the Company's common shares related to settlement of transaction consideration	—	840,398	—	—	—	—	—	—	—
Issuance of subsidiary preferred shares	—	—	—	—	—	—	—	70,000	70,000
Issuance of subsidiary common and preferred shares to the Company	—	—	—	(52,189)	—	—	—	52,189	—
Payment of subscription receivable	—	—	—	(40,000)	100,000	—	—	40,000	100,000
Cash contributions to majority-owned subsidiaries	—	—	—	(2,590)	—	—	—	2,590	—
Share-based compensation	—	—	—	386,568	—	—	—	10,744	397,312
Repurchase of equity awards	—	—	—	—	—	—	—	(2,247)	(2,247)
Foreign currency translation adjustment	—	—	—	—	—	2,488	—	57	2,545
Net loss	—	—	—	—	—	—	(208,481)	(17,159)	(225,640)
Balance at September 30, 2021	$ 22,491	684,789,169	$ —	$4,245,860	$ —	$ 1,281	$(2,209,126)	$ 390,393	$ 2,428,408

(1) Retroactively restated for the stock subdivision as described in Note 3.

	Redeemable Noncontrolling Interest	Shareholders' Equity(1)							
		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount						
Balance at March 31, 2020	$ 22,491	628,779,048	$ —	$3,143,739	$ —	$ (2,349)	$(1,109,228)	$ 54,042	$ 2,086,204
Issuance of subsidiary common shares, net of issuance costs	—	—	—	104,581	—	—	—	76,599	181,180
Issuance of subsidiary common shares to the Company	—	—	—	(6,342)	—	—	—	6,342	—
Exercise of subsidiary stock options	—	—	—	36	—	—	—	27	63
Deconsolidation of subsidiary	—	—	—	—	—	—	—	(3,054)	(3,054)
Repurchase of equity awards	—	—	—	(113)	—	—	—	—	(113)
Cash contribution to majority-owned subsidiaries	—	—	—	(149)	—	—	—	149	—
Share-based compensation	—	—	—	9,285	—	—	—	4,993	14,278
Foreign currency translation adjustment	—	—	—	—	—	(854)	—	34	(820)
Net loss	—	—	—	—	—	—	(3,243)	(4,734)	(7,977)
Balance at June 30, 2020	$ 22,491	628,779,048	$ —	$3,251,037	$ —	$ (3,203)	$(1,112,471)	$ 134,398	$ 2,269,761
Issuance of subsidiary common shares, net of issuance costs	—	—	—	101,418	—	—	—	74,499	175,917
Issuance of subsidiary common shares to the Company	—	—	—	(5,318)	—	—	—	5,318	—
Exercise of subsidiary stock options	—	—	—	69	—	—	—	50	119
Consolidation of unconsolidated entity	—	—	—	—	—	—	—	9,178	9,178
Cash contribution to majority-owned subsidiaries	—	—	—	(124)	—	—	—	124	—
Transfer (from) to noncontrolling interest	—	—	—	(255)	—	—	—	255	—
Share-based compensation	—	—	—	8,208	—	—	—	5,706	13,914
Foreign currency translation adjustment	—	—	—	—	—	(1,068)	—	34	(1,034)
Net loss	—	—	—	—	—	—	(35,398)	(18,100)	(53,498)
Balance at September 30, 2020	$ 22,491	628,779,048	$ —	$3,355,035	$ —	$ (4,271)	$(1,147,869)	$ 211,462	$ 2,414,357

(1) Retroactively restated for the stock subdivision as described in Note 3.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Six Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (326,718)	$ (61,475)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	72,107	41,779
Share-based compensation	416,581	28,192
Change in fair value of investments	(23,654)	(125,445)
Gain on sale of investment	(443,754)	—
Change in fair value of debt and liability instruments	17,730	27,273
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	(115,364)
Gain on termination of Sumitomo Options	(61,472)	—
Loss from equity method investment	—	3,750
Other	7,274	5,754
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Accounts payable	56,510	(29)
Accrued expenses	18,569	(12,912)
Operating lease liabilities	(2,537)	(2,621)
Other	7,598	1,886
Net cash used in operating activities	(261,766)	(209,212)
Cash flows from investing activities:		
Cash disposed upon deconsolidation of subsidiary	—	(19,085)
Cash acquired upon consolidation of unconsolidated entity	—	21,439
Investments in unconsolidated entities	—	(28,250)
Proceeds from sale of investment	320,170	—
Purchase of property and equipment	(5,100)	(1,609)
Net cash provided by (used in) investing activities	315,070	(27,505)
Cash flows from financing activities:		
Proceeds from Business Combination and PIPE Financing	213,424	—
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	—	357,017
Proceeds from payment of subscription receivable	100,000	—
Proceeds from subsidiary debt financings, net of financing costs paid	36,400	—
Repayment of long-term debt by subsidiary	(21,590)	—
Payment of offering and loan origination costs	(11,843)	—
Repurchase of equity awards	(2,247)	(113)
Proceeds from exercise of subsidiary stock options	—	182
Net cash provided by financing activities	314,144	357,086
Net change in cash, cash equivalents and restricted cash	367,448	120,369
Cash, cash equivalents and restricted cash at beginning of period	2,141,676	2,269,252
Cash, cash equivalents and restricted cash at end of period	$ 2,509,124	$ 2,389,621
Non-cash investing and financing activities:		
Operating lease right-of-use assets obtained and exchanged for operating lease liabilities	$ 4,579	$ 1,716
Offering costs included in accounts payable and accrued expenses	$ 8,453	$ 261
Other	$ —	$ (4,351)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ROIVANT SCIENCES LTD.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1—Description of Business and Liquidity

(A) Description of Business

Roivant Sciences Ltd. (inclusive of its consolidated subsidiaries, the "Company" or "RSL"), aims to improve health by rapidly delivering innovative medicines and technologies to patients. The Company does this by building biotech and healthcare technology companies ("Vants") and deploying technology to drive greater efficiency in research and development and commercialization. In addition to biopharmaceutical subsidiaries, the Company also builds technology Vants focused on improving the process of developing and commercializing medicines. The Company was founded on April 7, 2014 as a Bermuda exempted limited company.

The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company's subsidiaries are wholly owned subsidiaries and majority-owned or controlled subsidiaries. Refer to Note 4, "Investments" for further discussion of the Company's investments in unconsolidated entities.

On September 30, 2021, RSL completed its business combination with Montes Archimedes Acquisition Corp. ("MAAC"), a special purpose acquisition company, and began trading on Nasdaq under the ticket symbol "ROIV." Refer to Note 3, "Business Combination with MAAC" for additional details.

(B) Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of September 30, 2021, the Company had cash and cash equivalents of approximately $2.5 billion and its accumulated deficit was approximately $2.2 billion. For the six months ended September 30, 2021 and 2020, the Company incurred net losses of $326.7 million and $61.5 million, respectively. The Company has historically financed its operations primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates or take other steps to conserve capital. The Company expects its existing cash and cash equivalents will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation and Principles of Consolidation

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30, and December 31.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and follow the requirements of the Securities and Exchange Commission ("SEC") for interim financial reporting. Accordingly, these unaudited condensed consolidated financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the fiscal year ended March 31, 2021 issued on June 30, 2021. The unaudited condensed consolidated balance sheet at March 31, 2021 has been derived from the audited consolidated financial statements at that date. In the opinion of management, the unaudited condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the interim periods presented. Certain prior year amounts were reclassified to conform to current year presentation. Operating results for the three and six months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2022, for any other interim period, or for any other future year.

Any references in these notes to applicable accounting guidance are meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The unaudited condensed consolidated financial statements include the accounts of RSL and the subsidiaries in which it has a controlling financial interest, most often through a majority voting interest. All intercompany balances and transactions have been eliminated in consolidation.

For consolidated entities where the Company owns or is exposed to less than 100% of the economics, the Company records net loss attributable to noncontrolling interests in its unaudited condensed consolidated statements of operations equal to the percentage of common stock ownership interest retained in the respective operations by the noncontrolling parties. The Company presents noncontrolling interests as a component of shareholders' equity on its unaudited condensed consolidated balance sheets.

The Company accounts for changes in its ownership interest in its subsidiaries while control is retained as equity transactions. The carrying amount of the noncontrolling interest is adjusted to reflect the change in RSL's ownership interest in the subsidiary. Any difference between the fair value of the consideration received or paid and the amount by which the noncontrolling interest is adjusted is recognized within shareholders' equity attributable to RSL.

There have been no significant changes in the Company's accounting policies from those disclosed in the Company's audited consolidated financial statements for the fiscal year ended March 31, 2021 issued on June 30, 2021.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses, contingent liabilities, share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of September 30, 2021 and through the issuance of these condensed consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

(C) Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights.

(D) Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents. The Company maintains cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

(E) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Restricted cash classified as a current asset consists of legally restricted non-interest bearing deposit accounts relating to the Company's corporate credit card programs. Restricted cash classified as a long-term asset consists of restricted deposit accounts related to irrevocable standby letters of credit. As of March 31, 2021, restricted cash classified as a current asset included $75.0 million held in escrow for the purpose of fulfilling certain indemnification obligations. The full escrow amount of $75.0 million was disbursed to the Company in June 2021. See Note 6, "Sumitomo Transaction Agreement" for additional information.

Cash as reported in the condensed consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash as presented on the condensed consolidated balance sheets as follows (in thousands):

	September 30, 2021	March 31, 2021
Cash and cash equivalents	$ 2,497,330	$ 2,055,044
Restricted cash	11,794	86,632
Cash, cash equivalents and restricted cash	$ 2,509,124	$ 2,141,676

(F) Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses any litigation or other claims it may confront to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

(G) Investments

For investments in entities over which the Company has significant influence but do not meet the requirements for consolidation and for which the Company has not elected the fair value option, the Company applies the equity method of accounting with the Company's share of the underlying income or loss of such entities reported in "Other expense (income), net" on the condensed consolidated statements of operations. The Company applies the equity method to investments in common stock and to other investments in entities that have risk and reward characteristics that are substantially similar to an investment in the investee's common stock.

Investments in equity securities may also be accounted for using (i) the fair value option if elected, (ii) fair value through earnings if fair value is readily determinable or (iii) for equity investments without readily determinable fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

The Company has elected the fair value option to account for certain investments over which the Company has significant influence. The Company believes the fair value option best reflects the underlying economics of the investment. See Note 4, "Investments."

(H) Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as R&D. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. R&D costs primarily consist of the intellectual property and R&D materials acquired and expenses from third parties who conduct R&D activities on behalf of the Company.

The Company evaluates in-licensed agreements for in-process research and development projects ("IPR&D") to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as R&D expense in its condensed consolidated statements of operations. The Company initially recognizes contingent consideration in an asset acquisition at fair value. The carrying value of contingent consideration is subsequently adjusted when the contingency is resolved and is paid or becomes payable.

(I) Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include shares of common stock of Arbutus Biopharma Corporation ("Arbutus"); shares of Arbutus's Series A participating convertible preferred shares ("Arbutus Preferred Shares"); shares of common stock of Sio Gene Therapies Inc. ("Sio"); shares of common stock of Heracles Parent, L.L.C., the parent entity of the Datavant business, ("Datavant"); liability instruments issued, including warrant and earn-out shares liabilities issued in connection with the Company's business combination with MAAC (see Note 3, "Business Combination with MAAC"); deferred consideration liability; its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus and Sio common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. The Arbutus Preferred Shares held by the Company are classified as Level 2 as the fair value of such preferred shares is determined based upon the quoted market price of Arbutus common stock into which such preferred shares are convertible. The shares of Datavant common stock and liability instruments issued, excluding the Public Warrants (as defined and discussed in Note 3, "Business Combination with MAAC"), are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. The Public Warrants are publicly traded and therefore are classified as Level 1 as the Public Warrants have a readily determinable fair value. Cash, accounts payable, and deferred consideration liability are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The deferred consideration liability is based on a fixed monetary amount, and payment is based solely on the passage of time. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant Sciences Ltd. (together with its wholly owned subsidiaries, "Dermavant"), which is stated at amortized cost, approximates fair value based on current interest rates for similar types of borrowings and

therefore is included in Level 2 of the fair value hierarchy. Long-term debt issued by Dermavant for which the fair value option has been elected is included in Level 3 of the fair value hierarchy as the assumptions and estimates used in the valuation are unobservable in the market.

(J) Warrant Liabilities

The Company classifies the Roivant Warrants (as defined in Note 3, "Business Combination with MAAC") as liabilities. At the end of each reporting period, changes in fair value during the period are recognized within the condensed consolidated statements of operations. The Company will continue to adjust the liability associated with the Roivant Warrants for changes in the fair value until the earlier of a) the exercise or expiration of the Roivant Warrants or b) the redemption of the Roivant Warrants. Issuance costs incurred that were attributable to the Roivant Warrants were expensed as incurred.

(K) Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU No. 2020-06"). ASU No. 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP. ASU No. 2020-06 also removes certain settlement conditions that are required for equity contracts to qualify for the derivatives scope exception, which will permit more equity contracts to qualify for it. Either a modified retrospective transition method or a fully retrospective transition method is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The early-adoption of ASU No. 2020-06 on April 1, 2021 did not have a material impact on the Company's unaudited condensed consolidated financial statements.

Note 3—Business Combination with MAAC

On September 30, 2021 (the "Closing Date"), in accordance with the Business Combination Agreement, as amended (the "Business Combination Agreement"), RSL completed its previously announced business combination (the "Business Combination") with Montes Archimedes Acquisition Corp. ("MAAC"), through the merger of RSL's wholly-owned subsidiary, Rhine Merger Sub, Inc., with MAAC (the "Merger"), with MAAC surviving the Merger as a wholly owned subsidiary of RSL. As MAAC does not represent a business for accounting purposes and its primary asset represents cash and cash equivalents, the Business Combination was treated as an equity contribution in exchange for the issuance of RSL shares. The net assets of MAAC were stated at historical cost, with no goodwill or other intangible assets recorded. Reported amounts from operations included herein prior to the Business Combination are those of RSL.

On the Closing Date prior to the effective time of the Merger (the "Effective Time"), RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. The shares, equity awards and net loss per share available to holders of the Company's common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the fixed exchange ratio.

In accordance with the terms of the Business Combination Agreement, at the Effective Time:

a. each share of MAAC Class A common stock (the "MAAC Class A Shares") and each share of MAAC Class B common stock (the "MAAC Class B Shares" that were outstanding immediately before the Effective Time (other than treasury shares and any shares held by Patient Square Capital LLC (the "MAAC Sponsor"), any affiliate of the MAAC Sponsor or any of MAAC's independent directors (the "MAAC Independent Directors") or its transferee) were automatically canceled and extinguished and converted into one common share of RSL (the "Roivant Common Share"),

b. each MAAC Class B Share that was outstanding immediately before the Effective Time and held by the MAAC Sponsor, any affiliate of the MAAC Sponsor or any of the MAAC Independent Directors or its transferee were automatically canceled and extinguished and converted into a number of Roivant Common Shares based on an exchange ratio of 0.75, with a portion of such Roivant Common Shares issued to the MAAC Sponsor, any affiliate of the MAAC Sponsor, any MAAC Independent Director or its transferee by virtue of the Merger being subject to the vesting and other terms and conditions set forth in the Sponsor Support Agreement (as more fully described below),

c. each warrant to purchase MAAC Class A Shares that was outstanding immediately before the Effective Time was converted automatically into a right to acquire a Roivant Common Share (a "Roivant Warrant"), at an exercise price of $11.50 per share, subject to certain adjustments.

Following the Merger, the Roivant Common Shares and the Roivant Warrants began trading on the Nasdaq Global Market under the ticker symbols "ROIV" and "ROIVW," respectively, on October 1, 2021.

In connection with the Business Combination, RSL entered into subscription agreements with certain investors, whereby it issued 22,000,000 common shares at $10.00 per share for an aggregate purchase price of $220.0 million (the "PIPE Financing"). The PIPE Financing closed simultaneously with the consummation of the Business Combination.

In connection with the Business Combination and PIPE Financing, the Company received $213.4 million in cash at closing (the "Closing"), net of deferred underwriting expenses and unpaid expenses incurred by MAAC in connection with the transaction. The Company incurred $24.4 million in costs directly related to the Business Combination and PIPE Financing, such as banker fees and costs associated with third-party legal, accounting and other professional services. Upon Closing, these costs, which had been capitalized on the Company's balance sheet were recorded as a reduction of additional paid-in capital with the exception of $7.4 million, which were expensed as they represent the allocation of the transaction costs associated with the warrants and Earn-Out Shares (as defined below) liabilities. Transaction costs were allocated to the warrants and Earn-Out Shares liabilities based on the fair value of such instruments out of the total consideration.

Sponsor Support Agreement

Concurrently with the execution of the Business Combination Agreement, MAAC, the MAAC Sponsor, Roivant and each of the MAAC Independent Directors, entered into the Sponsor Support Agreement, which was subsequently amended on June 9, 2021, to reflect the MAAC Independent Directors and Roivant entering into respective Lock-Up Agreements, and further amended on September 30, 2021.

Pursuant to the Sponsor Support Agreement, among other things:

a. 2,033,591 Roivant Common Shares issued to the MAAC Sponsor and 10,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the "20% Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to $15.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).

b. 1,016,796 Roivant Common Shares issued to the MAAC Sponsor and 5,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the "10% Earn-Out Shares and together with the 20% Earn-Out Shares, the "Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to $20.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).

c. The remaining number of Roivant Common Shares issued to the MAAC Sponsor and each MAAC Independent Director are not subject to the vesting conditions described above (the "Retained Shares").

The Vesting Period represents the period commencing on the earlier of (a) the date on which the registration statement on Form S-1 required to be filed by the Company in connection with the PIPE Financing is declared effective or (b) November 15, 2021, and ending no later than the fifth anniversary of the Closing (the "Vesting Period"). The Vesting Period will, if a definitive purchase agreement with respect to a Sale (as defined in the Sponsor Support Agreement) is entered into on or prior to the end of such period, be extended to the earlier of one day after the consummation of such Sale and the termination of such definitive transaction agreement, and if a Sale occurs during such Vesting Period, then all of the Earn-Out Shares unvested as of such time will automatically vest immediately prior to the consummation of such Sale. If any Earn-Out Shares have not vested on or prior to the end of such Vesting Period, then such Earn-Out Shares will be forfeited.

The Earn-Out Shares meet liability classification requirements and are classified as "Liability instruments measured at fair value" on the condensed consolidated balance sheets. The Earn-Out Shares liability is subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company's statement of operations.

Lock-Up Agreements

On May 1, 2021 and June 9, 2021, RSL, on the one hand, and the MAAC Sponsor, the MAAC Independent Directors and certain Roivant equityholders, on the other hand, entered into lock-up agreements, pursuant to which, among other things, the MAAC Sponsor, the MAAC Independent Directors and such Roivant equityholders have agreed not to effect any sale or distribution of the Roivant Common Shares (including those underlying incentive equity awards or Roivant Warrants) held by the MAAC Sponsor, the MAAC Independent Directors or such equityholders as of immediately following the Closing during the applicable lock-up period, subject to customary exceptions.

The lock-up period applicable to Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors as of immediately following the Closing will be (i) with respect to 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, six months following the Closing, (ii) with respect to an additional 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, the earlier of twelve months following the achievement of certain price-based vesting restrictions or six years from the Closing and (iii) with respect to 50% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, thirty-six months following the Closing.

The Roivant Common Shares underlying warrants held by the MAAC Sponsor as of immediately following the Closing will be subject to a corresponding lock-up period for (a) with respect to 25% of such warrants held by the MAAC Sponsor, six months from the Closing, (b) with respect to an additional 25% of such warrants held by the MAAC Sponsor, twelve months from Closing and (c) with respect to 50% of such warrants held by the MAAC Sponsor, thirty-six months from the Closing.

The lock-up period applicable to Roivant Common Shares held by certain Roivant equityholders as of immediately following the Closing (including those underlying incentive equity awards) will be (x) with respect to 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), six months following the Closing, (y) with respect to an additional 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), twelve months following the Closing and (z) with respect to 50% of the Roivant Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, thirty-six months following the Closing.

Common Stock Warrants

At the effective time of the Merger, 10,214,365 Roivant Warrants that were held by the MAAC Sponsor at an exercise price of $11.50 (the "Private Placement Warrants") and 20,535,896 Roivant Warrants held by MAAC's shareholders at an exercise price of $11.50 (the "Public Warrants") were converted into the right to

acquire Roivant Common Shares. Pursuant to the agreement governing the Roivant Warrants, the Roivant Warrants became exercisable 30 days following the completion of the Business Combination. The Roivant Warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

The Private Placement Warrants are generally identical to the Public Warrants, except that (i) the Private Placement Warrants (including the common stock issuable upon exercise of the Private Placement Warrants) were not transferable, assignable or salable until 30 days after the completion of the Business Combination (ii) they will not be redeemable by the Company when the price per share of Roivant Common Shares equals or exceeds $18.00, and (iii) the Private Placement Warrants may be exercised by holders on a cashless basis. If the Private Placement Warrants are held by holders other than our sponsor or its permitted transferees, the Private Placement Warrants will be redeemable by Roivant in all redemption scenarios and exercisable by the holders on the same basis as the Public Warrants.

The Roivant Warrants meet liability classification requirements and are classified as “Liability instruments measured at fair value” on the condensed consolidated balance sheets. The Private Placement Warrants liability and Public Warrants liability are subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company’s statement of operations.

Redemption of Roivant Warrants when the price per share of Roivant Common Shares equals or exceeds $18.00.

Once the Roivant Warrants become exercisable, the Company may redeem the outstanding Roivant Warrants for cash (except with respect to the Private Placement Warrants):

- in whole and not in part;
- at a price of $0.01 per Roivant Warrant;
- upon a minimum of 30 days’ prior written notice of redemption; and
- if, and only if, the last reported sale price of common stock for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends the notice of redemption to the warrantholders (the “Reference Value”) equals or exceeds $18.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like).

However, in this case, the Company will not redeem the Roivant Warrants unless an effective registration statement under the Securities Act covering the Roivant Common Shares issuable upon exercise of the Roivant Warrants is effective and a current prospectus relating to those Roivant Common Shares is available throughout the 30-day redemption period. Any such exercise would not be on a “cashless” basis and would require the exercising warrantholder to pay the exercise price for each Roivant Warrant being exercised.

Redemption of Roivant Warrants when the price per share of Roivant Common Shares equals or exceeds $10.00.

Once the Roivant Warrants become exercisable, the Company may redeem the outstanding Roivant Warrants (except as described herein with respect to the Private Placement Warrants):

- in whole and not in part;
- at $0.10 per Roivant Warrant upon a minimum of 30 days’ prior written notice of redemption provided that holders will be able to exercise their Roivant Warrants on a cashless basis prior to redemption and receive that number of Roivant Common Shares determined by reference to an agreed table based on the redemption date and the “fair market value” of the Roivant Common Shares; and
- if, and only if, the Reference Value equals or exceeds $10.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like); and

- if the Reference Value is less than $18.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like), the Private Placement Warrants must also concurrently be called for redemption on the same terms (except as described herein with respect to a holder's ability to cashless exercise its warrants) as the outstanding Public Warrants, as described above.

For these purposes, "fair market value" of Roivant Common Shares shall mean the volume-weighted average price of common stock for the 10 trading days immediately following the date on which the notice of redemption is sent to warrantholders. In no event will the Roivant Warrants be exercisable in connection with this redemption feature for more than 0.361 Roivant Common Shares per Roivant Warrant (subject to adjustment).

Note 4—Investments

Investment in Arbutus

RSL owns 16,013,540 shares of common stock of Arbutus and 1,164,000 Arbutus Preferred Shares that are mandatorily convertible into shares of Arbutus common stock on October 18, 2021 subject to conversion earlier upon a sale, merger or other transaction considered a fundamental change of control of Arbutus. The Arbutus Preferred Shares are non-voting and are convertible into common shares of Arbutus based on the subscription price plus 8.75% per annum, compounded annually, divided by a conversion price of $7.13 per share (which represented a 15% premium to the closing price of $6.20 per share on September 29, 2017). The fair value option was elected to continuously remeasure the investment to fair value each reporting period after the initial measurement. Due to the Company's significant influence over operating and financial policies, Arbutus is considered a related party of the Company. At September 30, 2021, RSL held 29% of issued and outstanding shares of Arbutus, including the conversion of the Arbutus Preferred Shares held by RSL into common shares.

At September 30, 2021 and March 31, 2021, the aggregate fair value of the RSL investment in Arbutus was $166.7 million and $129.4 million, respectively. During the three and six months ended September 30, 2021, the Company recognized unrealized gains on its investments in Arbutus of $48.9 million and $37.3 million, respectively, in the accompanying condensed consolidated statements of operations. During the three and six months ended September 30, 2020, the Company recognized unrealized gains on its investments in Arbutus of $50.9 million and $82.4 million, respectively, in the accompanying condensed consolidated statements of operations. The fair value of the common stock and preferred shares held by the Company was determined using the closing price of Arbutus's common stock on September 30, 2021 and March 31, 2021 of $4.29 and $3.33, respectively.

On October 18, 2021, the Arbutus Preferred Shares were converted into Arbutus common stock. See Note 16, "Subsequent Events" for additional information.

Investment in Sio

Following the completion of Sio's underwritten public offering in February 2020, RSL's ownership interest fell below 50.0%. As such, the Company no longer has a controlling financial interest in Sio. Accordingly, the Company deconsolidated Sio in February 2020. Due to the Company's significant influence over operating and financial policies, Sio remains a related party of the Company following deconsolidation. As the Company still has the ability to exercise significant influence over the operating and financial policies of Sio, the Company has determined that its retained interest represents an equity method investment after the date of deconsolidation. Upon deconsolidation, the retained interest was recorded at fair market value based on the closing price of Sio's common stock. The fair value option was elected to continuously remeasure the investment to fair value each reporting period after the initial measurement. At September 30, 2021, RSL held 25% of Sio's issued and outstanding common shares.

At September 30, 2021 and March 31, 2021, the fair value of the Company's investment in Sio was $40.3 million and $48.5 million, respectively. During the three and six months ended September 30, 2021, the Company recognized unrealized losses on its investment in Sio of $10.4 million and $8.2 million, respectively, in the accompanying condensed consolidated statements of operations. During the three and six months ended September 30, 2020, the Company recognized unrealized gains on its investment in Sio of $33.4 million and $40.5 million, respectively, in the accompanying condensed consolidated statements of operations. The fair value of common shares held by the Company was determined using the closing price of Sio's common stock on September 30, 2021 and March 31, 2021 of $2.17 and $2.61, respectively.

Investment in Datavant

In April 2020, Datavant Holdings, Inc. ("Datavant") completed an initial round of a Series B equity raise by which 13,411,311 Series B preferred shares were issued in April 2020 for gross proceeds of $27.2 million, including 1,065,234 Series B preferred shares issued and sold to RSL for a total purchase price of $2.5 million and 1,800,253 Series B shares issued relating to the conversion of certain liability instruments. As a result of this transaction, along with a restructuring of Datavant's equity classes, RSL no longer controls Datavant. As such, the Company deconsolidated Datavant as of April 2020. Due to the Company's significant influence over operating and financial policies, Datavant remains a related party of the Company following deconsolidation. Upon deconsolidation, the Company recorded its investment in Datavant based on the fair value of Datavant preferred shares held of $99.0 million. Prior to the Datavant Merger (defined below), the Company accounted for its investment in Datavant using the measurement alternative to fair value. Under the measurement alternative, the investment is remeasured upon observable price changes in orderly transactions or upon impairment, if any. The Company recognized a gain on deconsolidation of $86.5 million in the accompanying condensed consolidated statements of operations for the six months ended September 30, 2020. In July 2020, Datavant issued and sold 639,140 Series B preferred shares to RSL at a price consistent with that of the initial round of Datavant's Series B equity raise, which resulted in an increase in the carrying value of our investment to $100.6 million.

In June 2021, Datavant and Heracles Parent, L.L.C. (referred to herein as "Ciox Parent" and, after the closing of the Datavant Merger (as defined below), "Datavant"), a provider of healthcare information services and technology solutions to hospitals, health systems, physician practices and authorized recipients of protected health records in the United States, primarily through its wholly owned subsidiary CIOX Health, LLC, entered into a definitive agreement to merge Datavant with and into a newly formed wholly-owned subsidiary of Ciox Parent (the "Datavant Merger"). The merger closed on July 27, 2021. At closing, the Company received approximately $320 million in cash and a minority equity stake representing approximately 17% of the outstanding Class A units in Ciox Parent. Ciox Parent's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted. As a result of the transaction, the Company recognized a gain on remeasurement of $443.8 million in the accompanying condensed consolidated statements of operations for the three and six months ended September 30, 2021.

Following the completion of the Datavant Merger, the Company's minority equity interest became subject to the equity method of accounting. At such time, the fair value option was elected to continuously remeasure the investment to fair value each reporting period with changes in fair value reflected in earnings. As of July 27, 2021 and September 30, 2021, the fair value of the Company's investment was $224.1 million and $220.0 million respectively, with the Company recognizing an unrealized loss on its investment of $4.1 million for the three and six months ended September 30, 2021. The fair value of the Company's investment was determined using valuation models that incorporate significant unobservable inputs and is classified as a Level 3 measurement within the fair value hierarchy. Refer to Note 13, "Fair Value Measurements" for more information.

Other Investment

The Company holds an additional equity investment that is measured using the fair value option. The fair value of this investment was $9.8 million and $11.1 million as of September 30, 2021 and March 31, 2021, respectively.

Note 5—Asset Acquisitions and License Agreements

In September 2021, a newly-formed subsidiary in-licensed certain intellectual property rights. The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The fair value of consideration transferred was $82.1 million, consisting of $70.0 million of preferred stock representing a dilution-protected minority ownership interest in the newly-formed subsidiary; a $10.0 million upfront cash payment; and $2.1 million relating to other obligations. The acquired rights, which included the licensed rights, starting materials and in-process inventory for each drug candidate, represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded $82.1 million as research and development expense in the accompanying condensed consolidated statements of operations for the three and six months ended September 30, 2021.

Additionally, the newly-formed subsidiary agreed to pay a future sales-based milestone payment and tiered royalties based on sales in the US and certain specified territories.

Note 6—Sumitomo Transaction Agreement

On December 27, 2019 (the “Sumitomo Closing Date”), RSL and Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) completed the transactions contemplated by the transaction agreement by and between RSL and Sumitomo, dated as of October 31, 2019 (the “Sumitomo Transaction Agreement”). Pursuant to the Sumitomo Transaction Agreement, RSL transferred its entire ownership interest in Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd. and Spirovant Sciences Ltd. (collectively, the “Sumitovant Vants”) to a newly formed, wholly-owned entity (“Sumitovant”).

RSL’s ownership interest in Sumitovant was then transferred to Sumitomo, such that following the Sumitomo Closing Date, Sumitovant and its subsidiaries, including the Sumitovant Vants, were each directly or indirectly owned by Sumitomo. Additionally, in connection with the Sumitomo Transaction Agreement, RSL (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of RSL’s ownership interests in six other subsidiaries (Dermavant, Genevant Sciences Ltd. (“Genevant”), Lysovant Sciences Ltd., Metavant Sciences Ltd., Roivant Asia Cell Therapy Holdings Ltd., and Sinovant Sciences HK Limited (collectively, the “Option Vants”)), (ii) (a) transferred the proprietary technology platform DrugOme to Sumitomo (for which RSL retains a perpetual royalty free license for internal use) and (b) licensed the Digital Innovation technology platform to Sumitomo (for which both parties retain ongoing access), and (iii) transferred 78,867,360 common shares of RSL to Sumitomo. On the Sumitomo Closing Date, the Company received approximately $2.9 billion in cash. Additionally, $75.0 million was deposited into a segregated escrow account for the purpose of fulfilling indemnification obligations of RSL that may become due to Sumitomo. The full escrow amount of $75.0 million was disbursed to the Company in June 2021. In connection with the Sumitomo Transaction, RSL’s board of directors approved an exchange and offer to repurchase RSL equity securities for up to $1.0 billion of the proceeds received from Sumitomo.

Concurrently with the Sumitomo Transaction Agreement, (i) RSL, Sumitomo and Sumitovant entered into a transition services agreement, whereby each of the parties thereto agreed to provide certain services to one another at cost for a period of time following the Sumitomo Closing Date and (ii) RSL and Sumitomo entered into a strategic cooperation agreement relating to certain ongoing technology-related collaborations between the parties. Pursuant to the terms of the transition services agreement and strategic cooperation agreement, RSL billed Sumitovant $0.3 million and $0.6 million, net of amounts billed by Sumitovant to RSL, during the three

and six months ended September 30, 2021, respectively. During the three and six months ended September 30, 2020, RSL billed Sumitovant $0.4 million and $0.8 million, net of amounts billed by Sumitovant to RSL, respectively, for costs incurred on behalf of Sumitovant, which were recorded as an offsets to the general and administrative (G&A) expenses initially charged. The period for certain services provided under the Transition Services Agreement expired in December 2020.

In conjunction with the Sumitomo Transaction, certain employees of the Company became employees of Sumitovant or its subsidiaries. The Company issued certain instruments to these employees that vest based on the achievement of time-based, performance or liquidity event requirements. As of September 30, 2021 and 2020, there were 5,164,558 and 5,470,387 outstanding instruments, respectively, held by Sumitovant employees for which aggregate fair value was recorded against the gain on sale of business.

In May 2021, the Company entered into an Asset Purchase Agreement with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (“SPC”) (the “Asset Purchase Agreement”). The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire the Company’s equity interests in the Option Vants (the “Sumitomo Options”); (ii) the Company transferred and assigned to SPC all of its intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively “Greater China”), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) Sumitomo agreed to pay the Company $5.0 million in cash; and (iv) Sumitomo entered into an agreement with the Company to pursue future collaborations with Genevant. The Company received the cash payment, net of certain withholding taxes, in August 2021. The Company recorded a gain on the termination of the Sumitomo Options of $66.5 million, consisting of the fair value of the Sumitomo Options on the date of termination and the expected cash payment, in the accompanying condensed consolidated statements of operations for the six months ended September 30, 2021.

Note 7—Balance Sheet Components

(A) Other Current Assets

Other current assets at September 30, 2021 and March 31, 2021 consisted of the following (in thousands):

	September 30, 2021	March 31, 2021
Prepaid expenses	$ 40,946	$ 39,544
Trade receivables, net	9,814	11,222
Income tax receivable	2,502	1,803
Other	2,301	1,681
Total other current assets	$ 55,563	$ 54,250

(B) Accrued Expenses

Accrued expenses at September 30, 2021 and March 31, 2021 consisted of the following (in thousands):

	September 30, 2021	March 31, 2021
Research and development expenses	$ 42,780	$ 20,755
Compensation-related expenses	20,965	38,552
Professional services expenses	17,325	10,267
Other general and administrative expenses	23,041	7,362
Total accrued expenses	$ 104,111	$ 76,936

(C) Other Current Liabilities

Other current liabilities at September 30, 2021 and March 31, 2021 consisted of the following (in thousands):

	September 30, 2021	March 31, 2021
Deferred revenue	$ 4,389	$ 5,918
Income tax payable	638	207
Other	5,630	3,037
Total other current liabilities	$ 10,657	$ 9,162

Note 8—Long-Term Debt and Loan Commitment

(A) Long-Term Debt

Long-term debt, net consists of the following (in thousands):

	September 30, 2021	March 31, 2021
Principal amount	$ 208,200	$ 170,100
Exit fee / end of term charge	5,000	1,390
Less: unamortized debt discount and issuance costs	(13,331)	(1,210)
Total debt, net	199,869	170,280
Less: current portion	—	—
Total long-term debt, net	$ 199,869	$ 170,280

Dermavant

In May 2019, Dermavant entered into a loan and security agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules"), pursuant to which Dermavant borrowed an aggregate of $20.0 million, which bore interest at a variable per annum rate at the greater of (i) 9.95% or (ii) the prime rate plus 4.45%. Dermavant was also obligated to pay an end of term charge of $1.4 million. Following the achievement of certain milestones, the term loan maturity was extended to June 1, 2023 with interest-only monthly payments through December 2021. All amounts outstanding under the Hercules Loan Agreement were repaid in May 2021 using the proceeds from a $40.0 million senior secured credit facility (the "Credit Facility") entered into by Dermavant and certain of its subsidiaries in May 2021 with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent. The Credit Facility has a five-year maturity and bears an interest rate of 10.0% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter through the maturity date. A lump sum principal payment is due on the maturity date. Dermavant is also obligated to pay an exit fee of $5.0 million. The exit fee can be reduced to $4.0 million upon achievement of certain equity milestones defined in the agreement, which are not deemed likely as of September 30, 2021. In connection with the funding of the Credit Facility, Dermavant issued a warrant to XYQ Luxco to purchase 1,199,072 common shares of Dermavant at an exercise price of $0.01 per common share.

In connection with Dermavant's acquisition of tapinarof from GlaxoSmithKline Intellectual Property Development Ltd. and Glaxo Group Limited (collectively "GSK") pursuant to an asset purchase agreement (the "GSK Agreement"), Dermavant and NovaQuest Co-Investment Fund VIII, L.P. ("NovaQuest") entered into a funding agreement (the "NovaQuest Agreement"). Pursuant to the NovaQuest Agreement, Dermavant borrowed $100.0 million in August 2018 and $17.5 million in October 2018 in exchange for an obligation to make certain variable future payments calculated as a function of the achievement of regulatory and commercial milestones or events of termination. The aggregate maximum amount of regulatory milestone payments that Dermavant could

be required to make under the NovaQuest Agreement is $440.6 million, and the maximum aggregate amount of commercial milestone payments is $141.0 million. In some circumstances, Dermavant may be able to offset certain of the regulatory milestone payments with up to $88.1 million of the commercial milestone payments. At issuance, the Company concluded that certain features of the long-term debt would be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, the Company has elected the fair value option for this financial instrument and will record the changes in the fair value within the statements of operations at the end of each reporting period. Direct costs and fees related to the debt issued under the NovaQuest Agreement were recognized in earnings. As of September 30, 2021 and March 31, 2021, the fair value of the debt was $168.2 million and $150.1 million, respectively. Refer to Note 13, “Fair Value Measurements” for additional details regarding the fair value measurement.

(B) Loan Commitment

In May 2021, Dermavant, as seller, entered into a $160.0 million revenue interest purchase and sale agreement (the “RIPSA”) for its investigational product tapinarof with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P. (collectively, the “Purchasers”), together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, the Purchasers procured a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States in exchange for $160.0 million in committed funding to be paid to Dermavant, conditional based on the approval of tapinarof by the FDA. The agreement will be canceled if funding has not occurred by July 2023. Dermavant acquired the worldwide rights to tapinarof (other than with respect to certain rights in China) in August 2018 pursuant to the GSK Agreement. Dermavant intends to use the RIPSA proceeds for the payment of certain one-time milestone obligations that become payable upon the approval and commercialization of tapinarof for the treatment of psoriasis in the United States as well as for other general corporate purposes.

Note 9—Shareholders’ Equity and Redeemable Noncontrolling Interest

(A) RSL Common Stock

In connection with the closing of the Business Combination, the Company adjusted its authorized share capital to equal 7,000,000,000 Roivant Common Shares, par value $0.0000000341740141 per share. Each Roivant Common Share has the right to one vote. The holders of Roivant Common Shares are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the board of directors since the Company’s inception.

On September 30, 2021 in connection with the closing of the Business Combination, RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. All per share amounts and number of shares in the condensed consolidated financial statements and related notes have been retroactively restated to reflect the stock split.

(B) Consolidated Vant Equity Transaction

Proteovant

In July 2021, Proteovant Sciences, Inc. (“Proteovant”) collected the subscription receivable relating to the second $100.0 million payment due under a subscription agreement entered into with SK, Inc. (“SK”) in December 2020 pursuant to which SK agreed to make a $200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date.

Note 10—Share-Based Compensation

(A) RSL 2021 Equity Incentive Plan

In September 2021, in connection with the Business Combination, the board of directors of RSL approved and adopted the 2021 Equity Incentive Plan (the "RSL 2021 EIP") and reserved 69,300,000 shares of common stock for issuance thereunder. The RSL 2021 EIP became effective immediately upon the closing of the Business Combination. The number of shares of common stock reserved for issuance under the RSL 2021 EIP will be increased annually on April 1 of each year during the term of the plan in an amount equal to the lesser of (i) 5% of the common shares outstanding as of the day of immediately preceding fiscal year and (ii) such number of common shares as determined by the board of directors of RSL in its discretion. Unless terminated sooner by the board of directors, the RSL 2021 EIP will automatically terminate on the day before the tenth anniversary of the effective date of the plan, being September 29, 2021. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards under the plan. Generally, each option will have an exercise price equal to the fair market value of the Company's common shares on the date of grant and a ten-year contractual term. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants. As of September 30, 2021, no grants have been made under the RSL 2021 EIP.

(B) RSL 2015 Equity Incentive Plan

Effective as of the closing of the Business Combination, no further awards will be granted under the RSL Amended and Restated 2015 Equity Incentive Plan (the "RSL 2015 EIP"). Any awards outstanding under the 2015 EIP as of the closing of the Business Combination remain subject to the terms of the RSL 2015 EIP and the applicable award agreement.

(C) Stock Options

The Company recorded share-based compensation expense of $12.3 million and $22.6 million for the three and six months ended September 30, 2021, respectively, and $8.0 million and $15.8 million for the three and six months ended September 30, 2020, respectively, related to stock options issued under the RSL 2015 EIP.

A summary of stock option activity and data under the RSL 2015 EIP for the six months ended September 30, 2021 is as follows:

	Number of Stock Options	Weighted Average Exercise Price
Stock options outstanding at March 31, 2021	27,474,942	$ 9.10
Granted	11,115,465	$ 10.00
Forfeited	(901,325)	$ 11.59
Stock options outstanding at September 30, 2021	37,689,082	$ 9.30
Stock options exercisable at September 30, 2021	18,999,834	$ 7.96

(D) Restricted Stock Units

Restricted stock units will generally vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date. Certain restricted stock units have also been granted

that will vest upon the achievement of development milestones and liquidity requirements. The liquidity event requirement was met upon closing of the Business Combination. Accordingly, the Company commenced recognition of share-based compensation expense for the restricted stock units on September 30, 2021. The Company recorded share-based compensation expense of $90.3 million for the three and six months ended September 30, 2021 related to restricted stock units issued under the RSL 2015 EIP. No share-based compensation expense was recorded during the three and six months ended September 30, 2020 as the liquidity event requirement had not been met and was deemed not probable of being met as of September 30, 2020.

A summary of restricted stock units under the RSL 2015 EIP is as follows:

	Number of Restricted Stock Units
Non-vested balance at March 31, 2021	6,708,799
Granted	18,369,012
Vested	(2,741,290)
Forfeited	(796,753)
Non-vested balance at September 30, 2021	21,539,768

Restricted stock units that have vested as of closing of the Business Combination and at any time prior to the expiration of the lockup are expected to be settled on the first business day immediately following expiration of the lock-up period (but in no event later than June 15, 2022). The lock-up is expected to expire on or about March 30, 2022.

(E) Performance Stock Options

Performance stock options (the “Performance Options”) will vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date of March 31, 2026. The liquidity event requirement was met upon closing of the Business Combination. Accordingly, the Company commenced recognition of share-based compensation expense for the Performance Options on September 30, 2021. The Company recorded share-based compensation expense of $262.5 million for the three and six months ended September 30, 2021 related to Performance Options issued under a special reserve of the RSL 2015 EIP (the “Special Reserve”) for the granting of Performance Options and capped value appreciation rights. No share-based compensation expense was recorded during the three and six months ended September 30, 2020 as the liquidity event requirement had not been met and was deemed not probable of being met as of September 30, 2020.

A summary of Performance Option activity and data under the RSL 2015 EIP for the three months ended September 30, 2021 is as follows:

	Number of Performance Options	Weighted Average Exercise Price
Performance Options outstanding at March 31, 2021	42,212,366	$ 13.30
Granted	—	$ —
Forfeited	—	$ —
Performance Options outstanding at September 30, 2021	42,212,366	$ 13.30
Performance Options exercisable at September 30, 2021	18,467,931	$ 13.30

(F) Capped Value Appreciation Rights

Capped value appreciation rights ("CVARs") will vest upon the achievement of both time-based service requirements and liquidity requirements on or before the grant expiration date of March 31, 2026. At settlement, each CVAR pays the excess in shares of (a) the lesser of (i) the fair market value of a common share as of the settlement date or (ii) the cap of $12.68, over (b) the hurdle price of either $6.40 or $11.50, as applicable to each grant. The liquidity event requirement was met upon closing of the Business Combination. Accordingly, the Company commenced recognition of share-based compensation expense for the CVARs on September 30, 2021. The Company recorded share-based compensation expense of $17.9 million for the three and six months ended September 30, 2021 related to CVARs issued under the Special Reserve. No share-based compensation expense was recorded during the three and six months ended September 30, 2020 as the liquidity event requirement had not been met and was deemed not probable of being met as of September 30, 2020.

A summary of CVARs under the RSL 2015 EIP is as follows:

	Number of CVARs
Non-vested balance at March 31, 2021	32,447,626
Granted	—
Vested	(14,195,849)
Forfeited	—
Non-vested balance at September 30, 2021	18,251,777

CVARs that have vested as of closing of the Business Combination and at any time prior to the expiration of the lockup are expected to be settled on the first business day immediately following expiration of the lock-up period (but in no event later than June 15, 2022). The lock-up is expected to expire on or about March 30, 2022.

(G) RSL 2015 Restricted Stock Unit Plan

Under the Amended and Restated RSL 2015 Restricted Stock Unit Plan (the "pRSU Plan"), as of September 30, 2021, there are 585,229 of the Company's common shares reserved for the granting under the pRSU Plan of restricted stock units ("Performance RSUs") to the Company's employees, officers, directors and consultants. The Performance RSUs expire eight years after the date of grant. Effective as of the closing of the Business Combination, no further awards will be granted under the pRSU Plan. Any awards outstanding under the pRSU Plan as of the closing of the Business Combination remain subject to the terms of the pRSU Plan and the applicable award agreement.

A summary of Performance RSU activity under the pRSU Plan is as follows:

	Number of Performance RSUs
Non-vested balance at March 31, 2021	585,229
Granted	—
Forfeited	—
Non-vested balance at September 30, 2021	585,229

These Performance RSUs will vest to the extent certain performance criteria are achieved and certain liquidity conditions are satisfied within specified years of the grant date, provided that the recipient has provided continued service through such date. The liquidity event requirement was met upon closing of the Business Combination. Accordingly, the Company commenced recognition of share-based compensation expense for the Performance RSUs on September 30, 2021. The Company recorded share-based compensation expense of $2.2 million for the three and six months ended September 30, 2021 related to the Performance RSUs issued

under the pRSU Plan. No share-based compensation expense was recorded during the three and six months ended September 30, 2020 as the liquidity event requirement had not been met and was deemed not probable of being met as of September 30, 2020.

(H) RSL Restricted Common Stock

A summary of RSL restricted common stock activity as of September 30, 2021 is as follows:

	Number of Restricted Common Stock
Non-vested balance at March 31, 2021	1,720,090
Granted	—
Forfeited	—
Non-vested balance at September 30, 2021	1,720,090

The Company recorded share-based compensation expense of $0.8 million and $1.6 million for the three and six months ended September 30, 2021, respectively, related to the RSL restricted common stock. The RSL restricted common stock will vest upon the achievement of time-based service requirements.

(I) Employee Stock Purchase Plan

In September 2021, the Company adopted the Roivant Sciences Ltd. Employee Stock Purchase Plan (the “RSL ESPP”), which provides for the granting of an option to purchase common shares of RSL to eligible employees, as defined by the RSL ESPP. The maximum number of common shares initially reserved and available for purchase under the RSL ESPP is 13,900,000. The total number of common shares available for purchase under the RSL ESPP will be increased annually on April 1 of each year during the term of the plan in an amount equal to the least of (i) 13,900,000 common shares, (ii) one percent of the aggregate number of common shares outstanding (on a fully diluted basis) on the last day of the immediately preceding Company fiscal year and (iii) such lesser number of common shares as determined by the board of directors; provided that the maximum number of common shares that may be issued under the RSL ESPP during the term of the plan is 147,447,650 common shares. As of September 30, 2021, no shares have been purchased under the RSL ESPP.

(J) Subsidiary Equity Incentive Plans

Certain wholly owned and majority-owned or controlled subsidiaries of RSL adopt their own equity incentive plan (“EIP”). Each EIP is generally structured so that the applicable subsidiary, and its affiliates’ employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted stock unit awards, and other share awards under their respective EIP. Standard option grants have time-based vesting requirements, generally vesting over a period of four years with a contractual term of ten years. Such time-based stock options use the Black-Scholes option pricing model. Standard restricted stock unit grants have time-based vesting requirements as well as liquidity event requirements for privately held subsidiaries. The grant date fair value of awards subject to market conditions is estimated using a Monte Carlo valuation model.

The Company recorded share-based compensation expense of $11.3 million and $19.5 million for the three and six months ended September 30, 2021, respectively, and $5.9 million and $12.4 million for the three and six months ended September 30, 2020, respectively, related to subsidiary EIPs.

(K) Share-Based Compensation Expense

Share-based compensation expense was as follows (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Share-based compensation expense recognized as:				
R&D expenses	$ 28,157	$ 1,887	$ 29,772	$ 3,006
G&A expenses	369,155	12,027	386,809	25,186
Total	$ 397,312	$ 13,914	$ 416,581	$ 28,192

Share-based compensation expense was included in R&D and G&A expenses in the accompanying condensed consolidated statements of operations. The classification of share-based compensation expense between R&D and G&A expenses in the accompanying condensed consolidated statements of operations is consistent with the classification of grantee's salary expense. The achievement of the liquidity event vesting condition for restricted stock units, Performance Options, and CVARs upon the closing of the Business Combination resulted in the recognition of a one-time catch-up expense of $372.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination.

Note 11—Income Taxes

The Company's effective tax rate for the three and six months ended September 30, 2021 was (0.2)% and (0.2)%, respectively, and the effective tax rate for three and six months ended September 30, 2020 was (1.3)% and (3.2)%, respectively. The effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of its deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary.

Note 12—Commitments and Contingencies

(A) Significant Agreements

The Company, primarily through its subsidiaries, has entered into commitments under various asset acquisition and license agreements. Additionally, the Company, through its subsidiaries, enters into agreements with contract service providers to assist in the performance of its R&D activities. Expenditures to contract research organizations and contract manufacturing organizations represent significant costs in the clinical development of its product candidates. Subject to required notice periods and certain obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(B) Loss Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated, and if the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation or claim, including an estimable range, if possible. The Company is currently not involved in any legal proceedings with a probable and estimable material loss.

(C) Intellectual Property Agreements

As of September 30, 2021, the Company did not have any ongoing material financial commitments, other than pursuant to various asset acquisition and license agreements.

(D) COVID-19 Pandemic

The Company has been actively monitoring the impact of the COVID-19 pandemic on its employees and business. Based on guidance issued by federal, state and local authorities, the Company transitioned to a remote work model for its employees in March 2020 and its workforce continues to primarily work remotely.

The COVID-19 pandemic has had a variable impact on clinical trials by disrupting certain study sites. In the conduct of business activities, the Company continues to take actions designed to protect the safety and well-being of its patients and employees. Although some of the Company's clinical development timelines have been impacted by delays related to the COVID-19 pandemic, the Company has not experienced material financial impacts on its business and operations as a result of the COVID-19 pandemic. However, the impact on the Company's future results will largely depend on future developments related to COVID-19, which are highly uncertain and cannot be predicted with confidence, such as the emergence of new variants, the ultimate duration and spread of the outbreak, the continuing impact of the COVID-19 pandemic on financial markets and the global economy, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain, treat, and prevent the disease, including the availability and effectiveness of vaccines.

Note 13—Fair Value Measurements

Recurring Fair Value Measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2021 and March 31, 2021, by level, within the fair value hierarchy (in thousands):

	As of September 30, 2021				As of March 31, 2021			
	Level 1	Level 2	Level 3	Balance as of September 30, 2021	Level 1	Level 2	Level 3	Balance as of March 31, 2021
Assets:								
Money market funds	$ 1,375,720	$ —	$ —	$ 1,375,720	$ 1,420,597	$ —	$ —	$ 1,420,597
Investment in Datavant Class A units	—	—	219,975	219,975	—	—	—	—
Investment in Sio common shares	40,313	—	—	40,313	48,487	—	—	48,487
Investment in Arbutus common shares	68,698	—	—	68,698	53,325	—	—	53,325
Investment in Arbutus convertible preferred shares	—	97,957	—	97,957	—	76,037	—	76,037
Other investment	9,837	—	—	9,837	11,129	—	—	11,129
Total assets at fair value	$ 1,494,568	$ 97,957	$ 219,975	$ 1,812,500	$ 1,533,538	$ 76,037	$ —	$ 1,609,575
Liabilities:								
Debt issued by Dermavant to NovaQuest	$ —	$ —	$ 168,200	$ 168,200	$ —	$ —	$ 150,100	$ 150,100
Liability instruments measured at fair value	30,599	—	44,685	75,284	—	—	67,893	67,893
Total liabilities at fair value	$ 30,599	$ —	$ 212,885	$ 243,484	$ —	$ —	$ 217,993	$ 217,993

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the six months ended September 30, 2021.

Level 3 Disclosures

The Company measures its Level 3 assets and liabilities at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the Level 3 assets and liabilities uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value related to updated assumptions and estimates are recorded within the statements of operations at the end of each reporting period.

The fair value of Level 3 assets and liabilities may change significantly as additional data are obtained, impacting the Company's assumptions regarding probabilities of potential scenarios used to estimate fair value. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. Accordingly, the use of different market assumptions and/or different valuation

techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The changes in fair value of the Level 3 assets during the six months ended September 30, 2021 were as follows (in thousands):

Balance at March 31, 2021	$ —
Fair value of investment in Datavant at recognition date	224,147
Changes in fair value of investment in Datavant, included in net loss	(4,172)
Balance at September 30, 2021	$219,975

There were no Level 3 assets held during the six months ended September 30, 2020.

The changes in fair value of the Level 3 liabilities during the six months ended September 30, 2021 and 2020 were as follows (in thousands):

Balance at March 31, 2020	$191,473
Changes in fair value of debt and liability instruments, included in net loss	27,273
Liability instruments disposed due to deconsolidation of subsidiary	(3,325)
Balance at September 30, 2020	$215,421
Balance at March 31, 2021	$217,993
Fair value of liability instrument issued	38,634
Changes in fair value of debt and liability instruments, included in net loss	17,730
Termination of DSP Options	(61,472)
Balance at September 30, 2021	$212,885

Investment in Datavant

The Company elected the fair value option to account for the investment in Datavant. The estimate of fair value for this investment was determined using an option pricing model ("OPM"). The OPM allows for the allocation of a company's equity value among the various equity capital owners (preferred and common shareholders). The OPM uses the preferred shareholders' liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date. The fair value was calculated using significant unobservable inputs including the following:

Input	Point Estimate Used As of September 30, 2021
Volatility	69.0%
Risk-free rate	0.2%

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of September 30, 2021 and March 31, 2021 represents the fair value of amounts payable to NovaQuest using the Monte Carlo simulation method under the income approach

determined by using probability assessments of the expected future payments through 2032 and applying discount rates ranging from 10% to 11%. The future payments are based on significant inputs that are not observable in the market which are subject to remeasurement at each reporting date. The estimates of fair value may not be indicative of the amounts that could ultimately be paid by Dermavant to NovaQuest.

Earn-Out Shares

The fair value of the Earn-Out Shares issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to include the lock-up periods to which the Earn-Out Shares are subject. Refer to Note 3, "Business Combination with MAAC" for additional details. Significant unobservable inputs used to calculate the fair value of the Earn-Out Shares included the following:

Input	Point Estimate Used As of September 30, 2021
Volatility	83.9%
Risk-free rate	0.98%

As of September 30, 2021, the fair value of the Earn-Out Shares was $21.3 million. Earn-Out Shares are included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Private Placement Warrants

The fair value of the Private Placement Warrants issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to incorporate the redemption features as discussed in Note 3, "Business Combination" and the added restriction by which the Company cannot redeem the Private Warrants if the Reference Value is greater than $18.00. Significant unobservable inputs used to calculate the fair value of the Private Placement Warrants included the following:

Input	Point Estimate Used As of September 30, 2021
Volatility	31.8%
Risk-free rate	0.98%
Term (in years)	5.0

As of September 30, 2021, the fair value of the Private Placement Warrants was $15.2 million. The Private Placement Warrants are included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Note 14—Other Expense (Income), Net

Other expense (income), net was as follows (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Loss from equity method investment	$ —	$ —	$ —	$ 3,750
Interest income	(62)	(579)	(133)	(1,200)
Interest expense	1,552	608	4,065	1,399
Other expense (income)	2,202	(786)	(374)	(1,864)
Total	$ 3,692	$ (757)	$ 3,558	$ 2,085

Note 15—Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss attributable to Roivant Sciences Ltd. by the weighted-average number of common stock outstanding during the period. Diluted net loss per common share is computed by dividing the net loss attributable to Roivant Sciences Ltd. by the diluted weighted-average number of common stock outstanding during the period.

For periods of loss, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common share equivalents is anti-dilutive. All outstanding common stock equivalents have been excluded from the computation of diluted loss per share because their effect was anti-dilutive due to the net loss.

As of September 30, 2021 and 2020, potentially dilutive securities were as follows:

	September 30, 2021	September 30, 2020
Stock options	37,689,082	27,788,039
Restricted stock units (non-vested)(1)	21,539,768	5,763,925
Performance stock options	42,212,366	42,212,366
Capped value appreciation rights(2)	32,447,626	32,447,626
Performance restricted stock units (non-vested)	585,229	585,229
Restricted common stock (non-vested)	1,720,090	—
Earn-Out Shares (non-vested)	3,080,387	—
Private Placement Warrants	10,214,365	—
Public Warrants	20,535,896	—
Other instruments issued	5,164,558	5,470,387

(1) Vested restricted stock units were treated as outstanding common shares for purposes of calculating net loss per common share for the three and six months ended September 30, 2021.

(2) Refer to Note 10, “Share-Based Compensation” for details regarding settlement of capped value appreciation rights. CVARs will be settled on the first business day immediately following expiration of the lock-up period.

Note 16—Subsequent Events

Investment in Arbutus

On October 18, 2021, the Arbutus Preferred Shares mandatorily converted into 22,833,922 shares of Arbutus common stock Common Shares in accordance with the terms of the subscription agreement entered into by RSL and Arbutus in October 2017. In connection with its acquisition of the Arbutus Preferred Shares, RSL had agreed to a four-year lock-up period and standstill period whereby, pursuant to the standstill, RSL would not acquire greater than 49.99% of the common shares of Arbutus or securities convertible into common shares. Both the lock-up and standstill periods expired on October 18, 2021. The Company will continue to account for its investment in Arbutus as an equity method investment accounted for using the fair value option.

17,407,773 Common Shares

PROSPECTUS

January 4, 2022