



roivant

2023

Annual Report

Dear Roivant Shareholders,

Ten years ago, Roivant was founded on the premise that inefficiencies in the biopharma industry can potentially lead to substantial return on investment through approaching drug development with the same principles with which a value investor approaches investing. We aimed to unlock these returns by acquiring drugs and making development decisions on a value-maximizing, capital-efficient basis. Reflecting on the last twelve months and on our 10th anniversary as a company, we are every bit as committed to this mission today as we were in 2014.

In many ways this past year – and in particular, through the development and sale of our Telavant subsidiary and RVT-3101– captured the founding spirit of Roivant unlike any other period in our company’s history. Following the acquisition of RVT-3101 at the end of 2022, we announced positive Phase 2b data in ulcerative colitis, built a Vant focused on delivering a compelling IBD therapy to patients, and then sold it to Roche for \$7.25B. True to our mission and to the culture of Roivant, we approached this opportunity with a value-first mindset, maximizing value for our shareholders and, I believe, for the patients who stand to benefit in the future from Roche’s continued development of this drug. Today, I am tremendously proud of the outcomes that this decision created for you, for the company, for our partners, and above all, for these patients.

In addition to RVT-3101, we extended our strong track record of meaningful clinical data over the past year, including positive data from the second Phase 3 study of VTAMA in atopic dermatitis, positive Phase 1 data and positive initial Phase 2 data in Graves’ Disease for IMVT-1402, and positive Phase 2 data for brepocitinib in non-infectious uveitis (NIU), where we generated arguably the strongest efficacy data in NIU observed to date. In total, we had 7 positive Phase 2 or 3 readouts in 2023 – an extraordinary hit rate for a company of our size and with our R&D spend. While there are no guarantees in the world of clinical data, I want to acknowledge the role our team and our company culture played in creating these outcomes. One thing I tell our team, as we reflect on these two different kinds of successes – transactional, financial success on the one hand and scientific progress for patients on the other – is that our field is full of companies that live and die on their own dogmas. They have profound commitments to specific ends – to furthering a given technology, to studying a specific disease, to commercializing their own medicines no matter the cost along the way. Roivant’s only dogma is that we have no dogma – we go where the science and our sense of value jointly lead us.

Finally, a few words on the year to come: These are unprecedented and tremendously exciting times for the company. On the pipeline expansion front, we are in a uniquely capital-rich position with access to some of the most interesting partnerships and technologies that exist in our field. Within our existing pipeline, we plan to initiate 4-5 potentially registrational programs at Immunovant and a Phase 3 pivotal trial of brepocitinib in NIU, with several significant clinical readouts along the way. We are grateful for your continued support and enthusiasm for these milestones to come.

We are creating value for patients, and we are doing work that matters. We have built a great company, and I am so excited for the next ten years.



Matt Gline | Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2024

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
For the transition period from _____ to _____
Commission File Number: 001-40782

ROIVANT SCIENCES LTD.

(Exact name of Registrant as specified in its Charter)

Bermuda
(State or other jurisdiction of
incorporation or organization)

98-1173944
(I.R.S. Employer
Identification No.)

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom
(Address of principal executive offices)

Not Applicable
(Zip Code)

+44 207 400 3347
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, \$0.000000341740141 per share	ROIV	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of September 29, 2023 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common shares, par value \$0.000000341740141 per share (the "common shares"), held by non-affiliates of the registrant was approximately \$8.0 billion, based on the closing price of the common shares on The Nasdaq Global Market on September 29, 2023 of \$11.68 per share.

As of May 28, 2024 there were 738,721,807 common shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement to be issued in conjunction with the registrant's 2024 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended March 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the registrant's proxy statement shall not be deemed to be a part of this Annual Report on Form 10-K.

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Summary Risk Factors

You should consider carefully the risks described under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. Unless the context otherwise requires, references in this section to “we,” “us,” “our,” “Roivant” and the “Company” refer to Roivant Sciences Ltd. and its subsidiaries and affiliates, as the context requires. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

Risks Related to Our Business and Industry

- Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development and commercialization may make it difficult for us to execute on our business model and for you to assess our future viability. We have generated limited revenue from our operations since inception, and there is no guarantee that we will generate significant revenues in the future.
- We may never achieve sustained profitability.
- We have relatively limited experience as a commercial-stage company and the marketing and sale of VTAMA® (tapinarof) or any future products may be unsuccessful or less successful than anticipated.
- Our business is dependent to a significant extent on the successful commercialization of VTAMA and the development, regulatory approval and commercialization of our current and future products and product candidates.
- We may not be successful in our efforts to acquire or in-license new product candidates, and newly acquired or in-licensed product candidates may not perform as expected in clinical trials or be successful in eventually achieving marketing approvals.
- We face risks associated with the allocation of capital and personnel across our businesses.
- We face risks associated with the Vant structure.
- We face risks associated with potential future payments related to our products and product candidates.
- Our business strategy and potential for future growth relies on a number of assumptions, some or all of which may not be realized.
- We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.
- We face risks associated with the use of our cash, cash equivalents and restricted cash, including any return of capital to shareholders.
- Clinical trials and preclinical 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 preclinical studies on the expected timelines, if at all.
- We may encounter difficulties enrolling and retaining patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.
- The results of our preclinical studies and clinical trials may not support our proposed claims for our products or 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.
- 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.
- 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 products or product candidates, our business will be substantially harmed.
- 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 products and 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.

- If we are unable to obtain and maintain patent and other intellectual property protection for our technology, products 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 products or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future products or product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our products. 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.
- Patent terms and their scope may be inadequate to protect our competitive position on current and future products and product candidates for an adequate amount of time.

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

- If our performance does not meet market expectations, the price of our securities may decline.
- We have incurred and will continue to incur increased costs as a result of operating as a public company and our management has devoted and will continue to devote a substantial amount of time to new compliance initiatives.
- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common shares may decline.
- Anti-takeover provisions in our memorandum of association and bye-laws, as well as provisions of 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 own a significant percentage of our common shares and are able to exert significant control over matters subject to shareholder approval.
- Future sales, or the perception of future sales, of our common shares by us or our existing shareholders could cause the market price for our common shares to decline and impact our ability to raise capital in the future.

Forward-Looking Statements

This Annual Report on Form 10-K contains statements, including matters discussed under Part I, Item 1A. “Risk Factors,” Part I, Item 3. “Legal Proceedings” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in other sections of this report, that are “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 Annual Report on Form 10-K 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 relatively limited experience as a commercial-stage company and ability to successfully commercialize VTAMA® (tapinarof);
- our ability to acquire or in-license new product candidates;
- the allocation of capital and personnel across our business;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- potential future payments related to our products and product candidates;

- our ability to consummate strategic transactions;
- the use of our cash and cash equivalents, including the proceeds from the Roche Transaction (as defined below);
- clinical trials and preclinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- the novelty, complexity and difficulty of manufacturing certain of our products and product candidates, including any manufacturing problems that result in delays in development or commercialization of our products and product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials, which could affect or otherwise delay clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- interim, top-line and/or preliminary data from our clinical trials changing as more data becoming available or data being delayed due to audit and verification processes;
- 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 an extensive, lengthy, expensive and inherently uncertain 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 our products and product candidates, including, but not limited to, scenarios in which our products and 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 or 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, products 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 current and future products and product candidates 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 products and product candidates and our inability to be certain that any of our other issued patents will provide adequate protection for such products and product candidates;
- the fact that our largest shareholders own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval;
- future sales of securities by us or our largest shareholders, or the perception of such sales, and the impact thereof on the price of our common shares;
- the outcome of any pending or potential litigation, including but not limited to our expectations regarding the outcome of any such litigation and costs and expenses associated with such litigation;
- changes in applicable laws or regulations;
- the possibility that we may be adversely affected by other economic, business and/or competitive factors; and
- any other risks and uncertainties, including those described under Part I, Item 1A. “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 Annual Report on Form 10-K, 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.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (<https://investor.roivant.com/>), SEC filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our shareholders and the public about our company, our products and product candidates and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Industry and Market Data

We obtained the industry and market data in this Annual Report on Form 10-K from our own research as well as from industry and general publications, surveys and studies conducted by third parties. Industry and general publications, studies and surveys generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. These third parties may, in the future, alter the manner in which they conduct surveys and studies regarding the markets in which we operate our business. As a result, you should carefully consider the inherent risks and uncertainties associated with the industry and market data contained in this Annual Report on Form 10-K, including those discussed in Part I, Item 1A. “Risk Factors.”

PART I

ITEM 1. BUSINESS

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

Overview

Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant’s pipeline is concentrated in inflammation and immunology and includes VTAMA, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting the neonatal Fc receptor (“FcRn”) in development across several IgG-mediated autoimmune indications; and brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 for the treatment of dermatomyositis and non-infectious uveitis, in addition to several other therapies in various stages of clinical development. We advance our pipeline by creating nimble subsidiaries or “Vants” to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business.

The following table summarizes selected commercial and development-stage pipeline products and product candidates.

Product/Product Candidate	Indication	Vant	Modality	Phase
VTAMA (tapinarof)	Psoriasis	Dermavant	Topical	Commercial
VTAMA (tapinarof)	Atopic Dermatitis	Dermavant	Topical	sNDA Filed
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 3*
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 3*
Batoclimab	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2*
Batoclimab	Graves’ Disease	Immunovant	Biologic	Phase 2
IMVT-1402	Numerous Indications	Immunovant	Biologic	Phase 1
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Non-Infectious Uveitis	Priovant	Small Molecule	Phase 2
Brepocitinib	Other Indications	Priovant	Small Molecule	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 2*
Undisclosed	Undisclosed Indications	New Vant	Undisclosed	Phase 2

Note: All clinical stage drugs in our current pipeline are investigational and subject to health authority approval. Pipeline reflects both ongoing clinical trials and expected upcoming trials.

* Indicates registrational or potentially registrational trials.

The Vant model unlocks key strategic advantages for Roivant and, we believe, ultimately enables us to develop transformative medicines for diseases for which there are no approved therapies or where the current standard of care treatment has significant limitations faster than our competitors. We believe we are uniquely positioned to accomplish this by:

- **Leveraging our business development expertise to identify and in-license promising drug candidates:** We assembled our development-stage product candidate pipeline by leveraging our business development expertise and vast network of industry relationships to relentlessly pursue opportunities to in-license or acquire programs where we believe we can deliver successful outcomes on accelerated timelines. Our pipeline expansion has been enabled by our strong track record of rapid and high-quality execution, as well as our ability to maintain a robust balance sheet to fund programs through development.
- **Creating nimble, entrepreneurial Vants:** Vants operate similarly to independent biotechnology companies where each management team is focused on its respective mission and is 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 its particular 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 outcomes of their specific products or 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 broad and differentiated pipeline that includes a commercial drug and several drug candidates 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 proven track record of developing successful 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.

The structural advantages of the Vant model combined with our “force of will” culture and investor mindset have enabled us to achieve an impressive track record: Since Roivant’s founding in 2014, we have commercialized VTAMA, the leading branded topical in psoriasis, developed six FDA-approved medicines and completed 11 large registrational Phase 3 studies – the last 10 of which have yielded positive data (inclusive of approvals and Phase 3 studies from Vants transferred to Sumitomo Pharma).

Recent Developments

In May 2024, Dermavant completed a renegotiation of its existing debt obligations to reduce its potential cash payments due under these obligations by over \$300 million in aggregate, of which an expected reduction of approximately \$225 million would be achieved over the next three fiscal years (the “Dermavant Debt Renegotiation”). For more information, see “Item 9B. Other Information.”

Key Business Highlights

- **Roivant**
 - o Announced the completion of the sale of Telavant to Roche for an upfront payment of approximately \$7.1 billion, with an additional \$150 million in cash payable upon the completion of a near-term milestone. Roivant’s net cash proceeds from the transaction were approximately \$5.2 billion. Approximately \$110 million of the additional milestone payment will be payable to Roivant following achievement.
 - o Roivant’s board of directors approved a share repurchase program for up to \$1.5 billion of the Company’s common shares; pursuant to this program, Roivant completed the repurchase of Sumitomo Pharma’s entire stake for approximately \$648 million.
- **VTAMA**
 - o Met the primary and all secondary endpoints in two Phase 3 studies and a long-term extension study, evaluating over 700 moderate-to-severe atopic dermatitis patients with no new safety or tolerability signals observed in this population, which included children as young as 2 years old.

- o Filed sNDA for VTAMA® (tapinarof) cream, 1% for the topical treatment of atopic dermatitis in adults and children 2 years of age and older. PDUFA action expected in the fourth quarter of calendar year 2024.
 - o Generated net product revenue of \$19.3 million and \$75.1 million for the fourth quarter and fiscal year ended March 31, 2024, respectively, with over 385,000 prescriptions written by over 15,300 unique prescribers since launch, as of May 2024.
- **Anti-FcRn Franchise**
 - o Reported results from Phase 1 SAD/MAD trials of IMVT-1402 that showed dose dependent and deep IgG reductions similar to batoclimab and minimal impact on albumin and low-density lipoprotein cholesterol.
 - o Reported an open-label Phase 2 proof-of-concept clinical trial of batoclimab in Graves' disease ("GD"). Subcutaneous doses of 680 mg of batoclimab administered in the initial cohort demonstrated potential best-in-class IgG reduction, up to 87%, with a mean IgG reduction of 81% after 12 weeks of treatment. The 340 mg IgG reductions were lower. Expected to announce detailed results from the study of batoclimab in GD as well as an overview of the development plan of IMVT-1402 in GD in the fall of 2024.
 - o Following a recently completed Type B meeting with the FDA, Immunovant is on track to initiate 4-5 potentially registrational studies with IMVT-1402 over the fiscal year ending March 31, 2025.
- **Brepocitinib**
 - o Reported results in the Phase 2 NEPTUNE study of once-daily oral brepocitinib in non-infectious uveitis ("NIU"), representing the best Treatment Failure rates observed to date among active NIU studies measuring this registrational endpoint.
 - o Ongoing pivotal study in dermatomyositis is on track to read out in calendar year 2025, and initiation of a pivotal program in NIU is expected in the second half of calendar year 2024.

Summary of Vant Milestone & Royalty Payments

The table below summarizes select potential future payment obligations from acquisitions, in-licensings and subsequent financings for select products and product candidates:

<u>Vant</u>	<u>Product or Product Candidate</u>	<u>Milestones</u>	<u>Royalties</u>
Dermavant	VTAMA (tapinarof)	<ul style="list-style-type: none"> • Up to CAD\$75M in remaining commercial milestones to Wellichem, with CAD\$35M payable upon VTAMA first U.S. commercial sale for atopic dermatitis and the remainder payable as first commercial sales are achieved in various ex-U.S. countries • Additional milestones owed to NovaQuest in connection with two 2018 financings that are accounted for as debt with a fair value of \$210M as of March 31, 2024 • Giving effect to the Dermavant Debt Renegotiation, the only remaining payments owed to NovaQuest are in the amount of \$122.5M in aggregate, to be paid between the fiscal years ending March 31, 2025 and March 31, 2029 • As a result of the Dermavant Debt Renegotiation, fixed quarterly payments totaling \$176.3M that would have been due and payable following regulatory approval of VTAMA (tapinarof) in the U.S. for atopic dermatitis, if approved, and payments of up to \$141.0M that would have been due and payable upon achievement of certain commercial milestones by Dermavant, have been eliminated 	<ul style="list-style-type: none"> • Low single-digit to high single-digit tiered percentage of quarterly revenues based on achievement of specified net sales thresholds, up to a \$344M cap, to be paid to an investor group in exchange for \$160M RIPSAs funding received in June 2022, following VTAMA approval; accounted for as debt with a net carrying value of \$195M as of March 31, 2024 • Giving effect to the Dermavant Debt Renegotiation, the RIPSAs now has a near-term cap on the royalties, equal to \$6M per fiscal year for each of the fiscal years ended March 31, 2025, 2026 and 2027. The Dermavant Debt Renegotiation did not otherwise amend the amount of the royalty payable to the RIPSAs Purchasers
Immunovant	Anti-FcRn Franchise	<ul style="list-style-type: none"> • Up to a maximum of \$420.0M (after an aggregate amount of \$32.5M of milestone achievements as of March 31, 2024) upon the achievement of certain development, regulatory and sales milestone events 	<ul style="list-style-type: none"> • Tiered royalties on net sales ranging from mid-single digits to mid-teens
Priovant	Brepocitinib	<ul style="list-style-type: none"> • Mid tens-of-millions sales milestone payment if aggregate net sales in a given year exceed a mid-hundred-of-millions amount 	<ul style="list-style-type: none"> • Tiered sub-teens royalty on net sales
Kinevant	Namilumab	<ul style="list-style-type: none"> • Up to \$40M upon the achievement of certain milestones 	<ul style="list-style-type: none"> • Tiered royalties on net sales ranging from sub-teens to mid-teens

Note: The summaries above do not purport to be complete. Please refer to “—Asset Acquisition and License Agreements; Other Vant Agreements” and the agreements themselves, filed as exhibits to this Annual Report on Form 10-K, for more information on the terms of these agreements.

Vant Ownership

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of March 31, 2024.

Vant	Roivant Ownership	
	Basic ¹	Fully Diluted ²
Dermavant	100% *	86% *
Immunovant	55% ³	49% ³
Priovant	75%	68%
Genevant	83%	65%
Kinevant	96%	90%
Covant	100%	87%
Psivant	48%	47%
Arbutus	22% ³	19% ³
Lokavant	57%	50%
VantAI	60%	49%
Datavant	**	**

1. Basic ownership refers to Roivant’s percentage ownership of the issued and outstanding common and preferred shares (if applicable) of the entity.
 2. Fully diluted ownership refers to Roivant’s percentage ownership of all outstanding equity interests of the entity, including unvested RSUs as well as options and warrants, in each case whether vested or unvested.
 3. Denotes entities that are publicly traded.
- * At closing of the Dermavant Debt Renegotiation and giving effect to the funding by Roivant of the full \$195 million preferred equity commitment made to Dermavant, Roivant will own approximately 87% of Dermavant’s issued and outstanding common and preferred shares and approximately 82% of Dermavant on a fully-diluted basis, inclusive of issued but unexercised warrants and options and restricted stock units held by current and former employees and other service providers (for purposes of this calculation, assuming no future incentive equity grants). For more information on the Dermavant Debt Renegotiation, see “Item 9B. Other Information.”
- ** As of March 31, 2024, the Company’s minority equity interest in Datavant represented approximately 9% of the outstanding Class A units. Datavant’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. For more information on Roivant’s ownership interest in Datavant, please refer to Note 4 to Roivant’s audited consolidated financial statements included in this Annual Report on Form 10-K.

Upcoming Catalysts

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

Program	Vant	Catalyst	Expected Timing
VTAMA (tapinarof) cream	Dermavant	Updates on commercial launch of VTAMA in psoriasis	Ongoing
Roivant pipeline growth	Roivant	New mid/late-stage in-licensing announcements	Ongoing
LNP platform	Genevant	Updates to LNP patent litigation	Ongoing
IMVT-1402/Batoclimab	Immunovant	Additional detailed results from the batoclimab trial in Graves' disease and overview of IMVT-1402 program	Fall 2024
Namulumab	Kinevant	Topline data from Phase 2 trial in sarcoidosis	4Q 2024
VTAMA (tapinarof) cream	Dermavant	FDA PDUFA action for sNDA of VTAMA in atopic dermatitis	4Q 2024
Batoclimab	Immunovant	Topline data from Phase 3 trial in myasthenia gravis & initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	By FY End
Batoclimab	Immunovant	Topline data from Phase 3 trials in thyroid eye disease	1H 2025
Brepocitinib	Priovant	Topline data from Phase 3 trial in dermatomyositis	2025

Note: References are to calendar years, unless otherwise specified. As used above, "FY" refers to Roivant's fiscal year. All catalyst timings are based on current expectations and, where applicable, contingent on FDA feedback, and may be subject to change.

Dermavant Overview

- **Overview:**

- Dermavant is marketing VTAMA® (tapinarof) cream, 1%, for the topical treatment of plaque psoriasis in adults. The FDA approved VTAMA for the topical treatment of mild, moderate and severe plaque psoriasis in May 2022. VTAMA has been the number one prescribed novel topical for plaque psoriasis since launch with over 385,000 prescriptions written by over 15,300 unique prescribers since launch, as of May 2024.
- Dermavant has filed a supplemental new drug application (sNDA) with the FDA for VTAMA for the treatment of atopic dermatitis in adults and children 2 years of age and older. FDA PDUFA action is expected in the fourth quarter of calendar year 2024.

- **Lead program:**

- VTAMA is a novel, once daily, steroid-free topical cream approved in the US for the treatment of plaque psoriasis in adults. Dermavant is developing VTAMA for the treatment of atopic dermatitis in adults and children as young as 2 years old.
- VTAMA 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.

- **Disease overview:**

- Plaque psoriasis is a chronic, inflammatory disease of the skin characterized by lesions consisting of 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 U.S., respectively. Out of approximately 560,000 weekly prescriptions across both diseases, approximately 100,000 and 340,000 are topical prescriptions for psoriasis and atopic dermatitis, respectively.

- **Limitations of current treatment:**

- Topical corticosteroids (“TCS”) are the most common first-line therapies but they typically cannot be used for longer than four weeks or in sensitive areas, such as face, groin, or axillae (armpit), due to the risk of significant side effects. 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 roflumilast, a non-steroidal PDE4 inhibitor, was approved in July 2022 for the treatment of plaque psoriasis in patients 12 years of age and older; however, this product carries label restrictions and contraindications, including a risk for drug interactions, and has not been shown to exhibit evidence of off-treatment remittive effect. 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 black box warnings of malignancy reported in patients treated with TCIs.
- While oral and biologic therapies have become increasingly available, they are often limited to moderate-to-severe disease with often complicated access, reimbursement and utilization management requirements. 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.

- **Clinical data:**

- We completed two pivotal Phase 3 clinical trials, PSOARING 1 and PSOARING 2, for the use of VTAMA in treating mild, moderate and severe plaque psoriasis in adults.
- In both pivotal Phase 3 trials, which enrolled over 500 patients each, VTAMA met its primary endpoint and secondary endpoints with clinically meaningful and statistically significant results. At week 12, 35.4% and 40.2% of patients treated with VTAMA 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 control cream (p<0.0001; p<0.0001).

- Our open-label, long-term extension study for plaque psoriasis, PSOARING 3, provides evidence of VTAMA’s increased therapeutic effect beyond the 12-week double-blind treatment periods, suggesting treatment durability over time, as well as evidence of a remittive effect, measured by time until disease worsening following treatment discontinuation.
- We completed two pivotal Phase 3 clinical trials, ADORING 1 and ADORING 2, that evaluated the use of VTAMA for the treatment of moderate to severe atopic dermatitis in adults and children as young as 2 years old. In both of these trials, which enrolled over 400 patients each, VTAMA met its primary endpoint and secondary endpoints with clinically meaningful and statistically significant results. At week 8, 45.4% and 46.4% of subjects receiving VTAMA achieved the primary endpoint of Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-ADTM) response of clear (0) or almost clear (1) with at least a 2-grade improvement from baseline, versus 13.9% and 18.0% on vehicle ($p < 0.0001$). The data indicated no new safety or tolerability signals in this population.
- We are also conducting ADORING 3, a long-term, open-label, extension study to evaluate the safety and efficacy of VTAMA cream 1% in patients with atopic dermatitis. Subjects in the study include those who have previously completed treatment with VTAMA or vehicle in ADORING 1 or ADORING 2, as well as subjects who have completed a pediatric maximal usage pharmacokinetics (MUPK) 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 consists of up to 48 weeks of VTAMA cream 1%, and a 7-day safety follow-up period. An interim analysis of the ADORING 3 extension study demonstrated that 51.2% (373/728) of patients achieved complete disease clearance (vIGA-AD score of 0).
- In our pediatric maximal usage pharmacokinetics (MUPK) study of VTAMA in atopic dermatitis, VTAMA demonstrated favorable safety, pharmacokinetics and clinical improvement in pediatric patients as young as 2 years old with extensive burden of atopic dermatitis.
- **Development plan and upcoming milestones:**
 - The FDA has accepted the sNDA for VTAMA for the treatment of atopic dermatitis in adults and children 2 years of age and older and assigned a PDUFA date in the fourth quarter of calendar year 2024.
- **Pricing and reimbursement:**
 - VTAMA had 138M US commercial lives (83% of total) covered as of May 2024.
 - VTAMA generated net product revenue of \$75.1 million for the fiscal year ended March 31, 2024, representing a 27% gross-to-net yield.
 - VTAMA’s wholesale acquisition cost has been \$1,445 per 60 gram tube since April 1, 2024.
- **Roivant ownership:**
 - As of March 31, 2024, we own 100% of the issued and outstanding common shares of Dermavant and 86% on a fully-diluted basis. Giving effect to the Dermavant Debt Renegotiation and giving effect to the funding by Roivant of the full \$195 million preferred equity commitment made to Dermavant, Roivant will own approximately 87% of Dermavant’s issued and outstanding common and preferred shares and approximately 82% of Dermavant on a fully-diluted basis, inclusive of issued but unexercised warrants and options and restricted stock units held by current and former employees and other service providers (for purposes of this calculation, assuming no future incentive equity grants). For more information on the Dermavant Debt Renegotiation, see “Item 9B. Other Information.”

Immunovant Overview

- **Overview:**

- Immunovant is pursuing a broad anti-FcRn strategy based on the potential best-in-class profile of the lead asset, IMVT-1402, that targets the neonatal fragment crystallizable receptor (“FcRn”), for the treatment of IgG-mediated autoimmune diseases.

- **Programs:**

- IMVT-1402 and batoclimab are novel, fully human monoclonal antibodies that target FcRn.
- Both were designed to be optimized as a simple, self-administered subcutaneous (“SC”) injection with dosing that we believe can be tailored based on disease severity and stage.
- IMVT-1402 has been observed in Phase 1 studies to have dose dependent and deep IgG reductions and minimal impact on albumin and low-density lipoprotein (“LDL”) cholesterol. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe IMVT-1402 has the potential for broad application in related disease areas.
- For IMVT-1402, we are on track to initiate 4-5 potentially registrational programs by March 31, 2025, and, inclusive of these programs, plan to have initiated trials in 10 indications by March 31, 2026. We currently have ongoing studies with batoclimab in myasthenia gravis (“MG”), thyroid eye disease (“TED”), chronic inflammatory demyelinating polyneuropathy (“CIDP”) and Graves’ disease (“GD”). The current development program for batoclimab will help accelerate and optimize the registrational development program of IMVT-1402.

- **Disease overview:**

- Neurological Diseases

- MG is a rare, chronic autoimmune disorder characterized by weakness and fatigue of voluntary muscles. The estimated prevalence of MG is 18 to 36 per 100,000, with up to 59,000 to 116,000 people in the U.S.
- CIDP is an autoimmune neurological disorder characterized by damage to the myelin sheaths or the nodes on nerve fibers of the peripheral nervous system. CIDP has an estimated prevalence of almost nine per 100,000 people in the US.

- Endocrine Diseases

- GD is an autoimmune disorder associated with the overproduction of thyroid hormones and is the most common cause of hyperthyroidism. GD has an estimated incidence of 20 to 50 per 100,000 people in the US.
- TED is an autoimmune disorder affecting the tissues around the eyes, and in severe cases can be sight-threatening. TED has an estimated annual incidence of 10 per 100,000 people in the U.S.

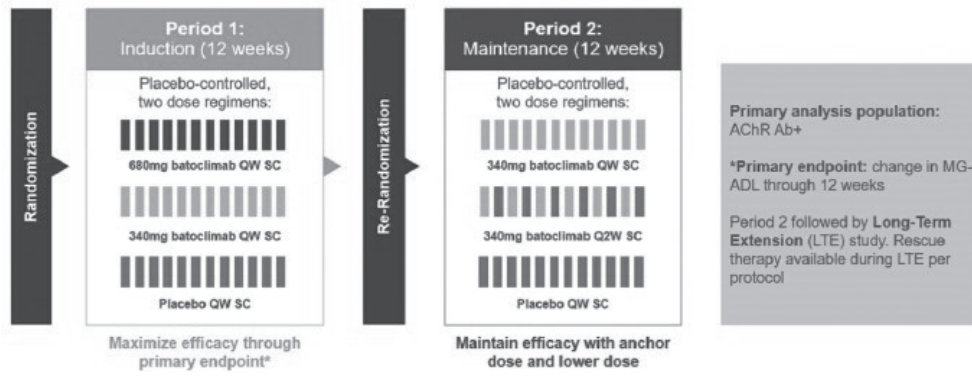
- **Limitations of current treatments:**

- For many IgG-mediated autoimmune diseases, early-stage disease control involves corticosteroids and immunosuppressants, later progressing to intravenous immunoglobulin (“IVIg”) or plasma exchange. These approaches are generally limited by delayed onset of action, waning therapeutic benefit over time, and unfavorable safety profiles.
- Recent agents approved for MG include eculizumab and ravulizumab-cwvz, two complement C5 inhibitors, efgartigimod, an anti-FcRn antibody fragment, and rozanolixizumab, a monoclonal antibody. We believe there is room to improve upon this current treatment paradigm for MG, as some of these treatments can leave patients with burdensome administration requirements, significant side effects or long wait times to see treatment effect.
- There remains significant unmet medical need for patients with CIDP. Although immunoglobulin therapy (IVIg, SCIG) is effective, it may be associated with significant side effects and complications such as severe headache, thromboembolism, and hemolysis. Corticosteroid therapy, though effective, has well-known serious adverse events (e.g., weight gain, hypertension, diabetes, and osteoporosis), especially with chronic use. The immunomodulatory therapies that may be used in CIDP are all associated with significant potential risks, including the possibility of malignancy and/or infection.

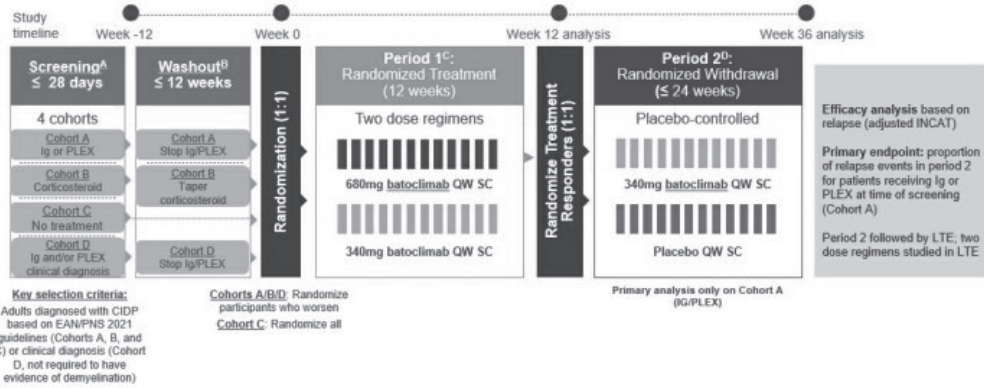
- The main treatment goal of GD is to reduce thyroid hormone levels. There are three options available: surgery, RAI, and oral antithyroid drugs (“ATDs”). Surgery may lead to an immediate resolution of the hyperthyroidism, but it is associated with a number of complications, including parathyroid gland injury, which may lead to transient or persistent hypocalcemia, and damage of the laryngeal nerve. Treatment with RAI destroys the thyroid because ionizing radiation causes deoxyribonucleic acid damage. Recent data suggest an association between RAI radioiodine and several types of cancer. While ATDs are considered generally safe, their chronic use can be associated with hepatotoxicity, pancreatitis and bone marrow toxicity.
- Surgery is considered to be a treatment option in patients with a highly active disease who have been treated with corticosteroids or immunosuppressive therapy but continue to have progressive disease. Because of its invasive nature, surgery is typically reserved for inactive disease. TEPEZZA® (teprotumumab), an anti-IGF-1R antibody, was approved for the treatment of TED in 2020. As reflected in the updated prescribing information for TEPEZZA, IGF-1R inhibition may be associated with hearing loss.
- **Clinical data:**
 - In December 2023, we announced initial MAD results from the cohort of participants receiving a weekly subcutaneous dose of 600 mg in the Phase 1 clinical trial of IMVT-1402. After four weekly subcutaneous doses of IMVT-1402, we observed a statistically significant reduction of 74% from baseline in mean total IgG levels, similar to the 76% reduction in mean total IgG levels observed in the Phase 1 clinical trial of batoclimab after four weekly doses of 680 mg given subcutaneously. After four weekly subcutaneous doses of 600 mg IMVT-1402, no or minimal reductions in albumin and no or minimal increases in LDL cholesterol levels were observed, which were consistent with those receiving placebo.
 - In December 2023, we reported an open-label Phase 2 proof-of-concept clinical trial of batoclimab in Graves’ disease. Subcutaneous doses of 680 mg of batoclimab administered in the initial cohort demonstrated potential best-in-class IgG reduction, up to 87%, with a mean IgG reduction of 81% after 12 weeks of treatment. The 340 mg IgG reductions were lower. This trial is ongoing.
- **Development plan and upcoming milestones:**
 - For IMVT-1402, we are on track to initiate 4-5 potentially registrational programs by March 31, 2025, and, inclusive of these programs, plan to have initiated trials in 10 indications by March 31, 2026
 - We expect to announce an overview of the development plan for IMVT-1402 in GD in the fall of calendar year 2024, supported by additional data from the batoclimab proof-of-concept study in GD that will be disclosed at the same time.
 - We may transition our registrational development program for CIDP from batoclimab to IMVT-1402 and the pivotal study with IMVT-1402 in CIDP may be optimized based on unblinded batoclimab CIDP data available by March 31, 2025.
 - We expect to report top-line data from the batoclimab MG study by March 31, 2025 with potentially registrational development for MG with IMVT-1402 expected to begin in the same timeframe.
 - We expect top-line data from the Phase 3 pivotal trial of batoclimab as a treatment for TED and a decision regarding which asset to advance to registration to be available in the first half of calendar year 2025.

The below schematics show the trial designs for the ongoing batoclimab trials:

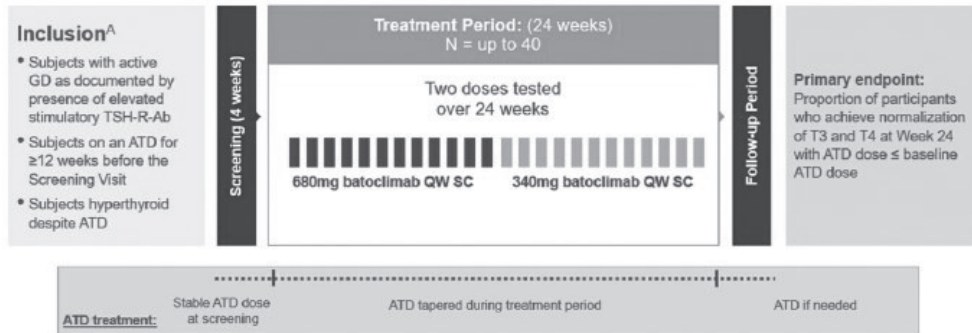
MG Phase 3 Trial Design (N ~ 210)



CIDP Phase 2b Trial Design

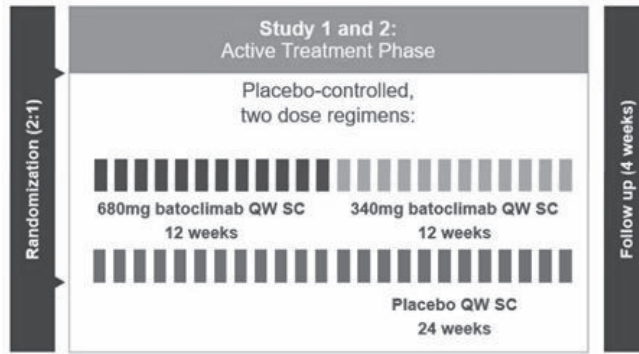


GD Phase 2 Trial Design



A: Additional inclusion and exclusion criteria not listed

TED Phase 3 Trial Design



- **Roivant ownership:**

- As of March 31, 2024 we own 55% of the issued and outstanding shares of Immunovant common stock and 49% on a fully diluted basis.

Priovant Overview

Overview:

- Priovant is developing brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1, for the treatment of dermatomyositis (“DM”), non-infectious uveitis (“NIU”), and other immune-mediated diseases.

Lead program:

- Brepocitinib is a potentially first-in-class, orally administered, small molecule inhibitor of TYK2 and JAK1 that suppresses signaling of TYK2- and JAK1-dependent cytokines linked to autoimmune disease, including type I and type II interferon, IL-6, IL-12, and IL-23.

Disease overview:

- DM is a chronic, immune-mediated disease of the skin and muscles. Patients with DM usually present with a characteristic skin rash and proximal muscle weakness, which may lead to significant functional impairment or disfigurement. Patients with DM are at a substantially increased risk of interstitial lung disease, malignancy, and heart failure, contributing to an estimated 5-year mortality rate of 10-40%.
- NIU is an immune-mediated disease of the eye. Patients with NIU usually present with eye inflammation, which can manifest as eye pain, eye redness, light sensitivity, blurred vision, reduced vision, and/or floaters. Patients with NIU are at a substantially increased risk of blindness, contributing to approximately 10% of cases of blindness in the U.S.
- We estimate that there are approximately 37,000 adult DM patients and approximately 400,000 adult NIU patients in the US, including 70-100,000 adult non-anterior NIU patients.

Limitations of current treatments:

- Corticosteroids, disease-modifying antirheumatic drugs (“DMARDs”), and immunosuppressants, administered alone or in combination, are traditional therapies for patients with DM and NIU. Many of these therapies are associated with significant toxicities and limited efficacy.
- For patients with DM who do not respond adequately to traditional therapies, IVIg (OCTAGAM 10%) is an important FDA-approved treatment. However, clinical trial data from the Phase 3 ProDERM study of IVIg in patients with DM and case reports from years of prior off-label use confirm that even with IVIg, many patients with DM continue to suffer from residual disease activity. Moreover, IVIg administration is burdensome, typically requiring several hours of infusion therapy for multiple days each month. IVIg also has a black box warning for serious risks, including thrombosis and kidney failure.
- For patients with NIU who do not respond adequately to traditional therapies, adalimumab (HUMIRA) administered subcutaneously, is the only FDA-approved modern treatment. NIU patients treated with HUMIRA have failure/relapse rates of approximately 50%, indicating a large unmet need for more efficacious treatment options.

Clinical data:

- Brepocitinib has been evaluated in seven positive completed Phase 2 studies in immune-mediated diseases (alopecia areata, psoriatic arthritis, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, Crohn’s disease and non-infectious uveitis). In the six placebo-controlled studies, treatment with brepocitinib was associated with statistically significant and clinically meaningful efficacy. In the Phase 2 NEPTUNE proof-of-concept study, brepocitinib demonstrated the best Treatment Failure rates observed to date among active NIU studies measuring this registrational endpoint.

Study Population	N1	Brepocitinib Dose	Primary Endpoint Result	Statistical Significance
Alopecia Areata	942	30 mg once daily ³	49.18 placebo-adjusted CFB in SALT Score at week 24	P < 0.0001 ⁴
Psoriatic Arthritis	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	P = 0.0197
Ulcerative Colitis	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	P = 0.0005
Plaque Psoriasis	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI score at week 12	P < 0.0001
Hidradenitis Suppurativa	100	45 mg once daily ⁵	18.7% placebo-adjusted HiSCR Rate at week 16	P = 0.0298 ⁴
Crohn's Disease	151	60 mg once daily ⁶	21.4% placebo-adjusted SES-CD 50 Rate at week 12	P = 0.0012 ⁴
Non-infectious Uveitis	26	45 mg once daily	29.4% Treatment Failure Rate at week 24	

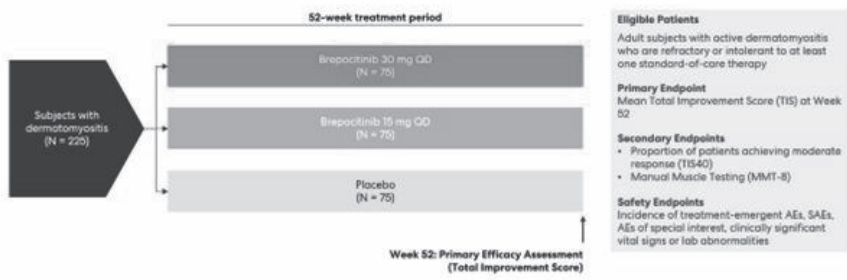
1. Overall study N represents patients randomized to all brepocitinib dose levels or placebo and excludes patients randomized to other agents.
2. Includes patients from initial 24-week study period only.
3. 60 mg once daily for 4 weeks followed by 30 mg once daily for 20 weeks.
4. One-sided p-value (pre-specified statistical analysis).
5. Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study.
6. Brepocitinib 60 mg once daily was the only brepocitinib dose evaluated in the induction period of this study.

The non-infectious uveitis study was conducted by Priovant; all other brepocitinib studies shown here were conducted by Pfizer.

ACR20: American College of Rheumatology 20% Improvement; RR: Response Rate; CFB: Change From Baseline; PASI: Psoriasis Area and Severity Index; SALT: Severity of Alopecia Tool; HiSCR: Hidradenitis Suppurativa Clinical Response; SES-CD: Simple Endoscopic Score for Crohn's Disease

- Brepocitinib's safety database includes over 1,400 exposed participants evaluated in completed and ongoing clinical studies. In these studies, brepocitinib was generally safe and well-tolerated, and rates of JAK class treatment-emergent adverse events ("TEAEs") of interest were comparable to those observed in the development programs of approved JAK inhibitors. Collectively, these data suggest a safety profile that is similar to those of approved JAK inhibitors.
- In the Phase 2 NEPTUNE study of once-daily oral brepocitinib in NIU, the 45 mg results represented the best Treatment Failure rates observed to date among active NIU studies measuring this registrational endpoint. On the pre-specified primary efficacy endpoint of Treatment Failure at week 24, 29% of subjects receiving brepocitinib 45 mg and 44% of subjects receiving brepocitinib 15 mg met Treatment Failure criteria (lower failure rates reflect greater treatment benefit). The Treatment Failure rate from disease activity (discontinuations censored) was 18% in the brepocitinib 45 mg arm. All secondary efficacy endpoints were also positive and dose responsive, including measurements of potential benefit on prevention and treatment of uveitic macular edema. Brepocitinib was generally safe and well-tolerated in the study, with no new safety and tolerability signals identified.
- Brepocitinib has not been evaluated in DM to date. However, several FDA-approved JAK inhibitors have been clinically validated in DM patients refractory to standard-of-care therapies, as reported in more than 100 off-label case reports and in an open-label clinical trial. In addition, since DM pathobiology is driven by dysregulations in cytokines whose signaling is mediated by both TYK2 and JAK1, we believe that, with its unique dual inhibition of both TYK2 and JAK1, brepocitinib, as compared to inhibitors selective to either TYK2 or JAK1, has the potential to demonstrate superior clinical efficacy in DM.
- **Development plan and upcoming milestones:**
 - Priovant is currently conducting a large randomized, controlled Phase 3 study of brepocitinib in patients with refractory dermatomyositis. This study will enroll approximately 225 subjects in total and will evaluate 15 mg and 30 mg of brepocitinib once-daily compared to placebo. The primary endpoint of this study is the mean Total Improvement Score ("TIS"), a validated myositis improvement index, at Week 52. Topline data is expected in calendar year 2025.
 - Priovant is currently planning a Phase 3 study in non-infectious uveitis that is expected to initiate in the second half of calendar year 2024.
 - Priovant is also evaluating brepocitinib for development in other orphan and specialty immune-mediated diseases.

The below schematics show the trial designs for the ongoing DM Phase 3 trial:



Roivant ownership:

- As of March 31, 2024, we own 75% of the issued and outstanding shares of Priovant and 68% on a fully diluted basis.

Kinevant Overview

- **Overview:**

- Kinevant is focused on developing namilumab for sarcoidosis and potentially other diseases.

- **Lead program:**

- Namilumab is a fully human anti-GM-CSF monoclonal antibody with broad potential in inflammatory and autoimmune diseases being developed with potentially the least frequent dosing schedule among subcutaneous anti-GM-CSFs in Phase 2 clinical trial, with a single dose every four weeks after an initial loading period.

- **Disease overview:**

- Sarcoidosis is a multi-system inflammatory disease characterized by the presence of non-necrotizing granulomas believed to be formed by an exaggerated immune response to unidentified antigens. Sarcoidosis primarily affects the lungs and lymphatic system, though sarcoidosis may damage any organ. GM-CSF, a key pathogenic cytokine, has been implicated in multiple parts of the granulomatous response.
- Sarcoidosis affects approximately 200,000 people in the U.S., with over 90% of cases presenting with pulmonary involvement.
- An estimated 54% of pulmonary sarcoidosis patients are diagnosed, and approximately 90% of these patients receive some form of treatment. 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.

- **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.

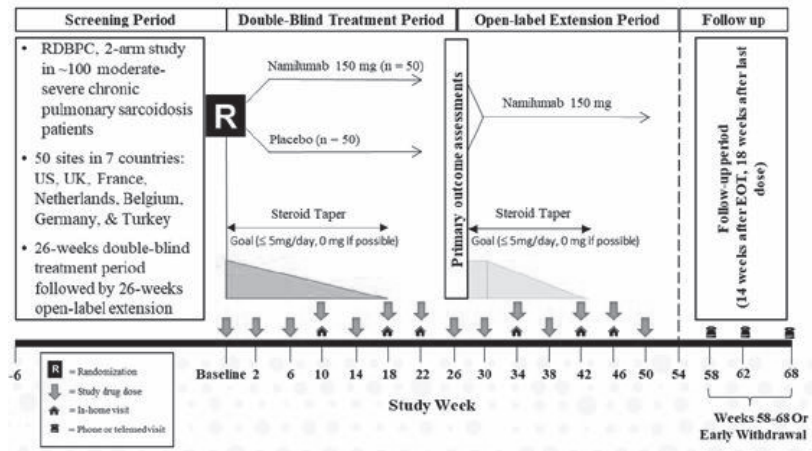
- **Clinical data:**

- 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.
- In a Phase 1 study of healthy volunteers with a single subcutaneous injection, namilumab was observed to be generally well-tolerated.
- In a Phase 2 trial in patients with moderate to severe rheumatoid arthritis 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. 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 were nasopharyngitis, dyspnea, bronchitis, and headache.

- **Development plan and upcoming milestones:**

- We have completed enrollment for a Phase 2 trial to evaluate the safety and efficacy of namilumab in pulmonary sarcoidosis, with data expected in the fourth quarter of calendar year 2024.

The below schematic shows the trial design for the Phase 2 trial in pulmonary sarcoidosis:



Roivant ownership:

- o As of March 31, 2024, we own 96% of the issued and outstanding common shares of Kinevant, and 90% on a fully diluted basis.

Genevant Overview

• Overview:

- Genevant is a technology-focused nucleic acid delivery and development company with two delivery platforms—a lipid nanoparticle (“LNP”) platform and a ligand conjugate 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 and patent portfolio:

- 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 in various stages of development for other traditionally hard-to-reach tissues and cell types, including lung, eye, central nervous system, and hepatic stellate and immune cells.
 - Approximately 650 issued patents and pending patent applications as of March 31, 2024, including patents directed to:
 - lipid structures, including cationic and PEG-lipids
 - particle compositions, including commonly used 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
 - 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 novel extrahepatic ligands to expand therapeutic reach.

• Collaboration-based business model:

- 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 its therapeutic application.
- 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’s collaboration-based business model is to seek upfront payments, R&D reimbursements, milestones and royalties payment or profit sharing upon success, while also retaining certain rights in the delivery-related intellectual property developed in the context of the collaboration for potential use or out-licensing.
- Some current collaboration partners include Novo Nordisk, BioNTech, Takeda, Gritstone, Tome Biosciences, ST Pharm, Korro Bio, Chulalongkorn University (through its Vaccine Research Center) and Providence Therapeutics.

• Clinical and preclinical data:

- Genevant LNP technology has been in clinical testing in over a dozen distinct product candidates, representing hundreds of subjects of clinical experience.
- In a head-to-head study comparing multiple LNP formulations varying only the key ionizable lipid, Genevant’s current lead formulation outperformed third-party formulations. Our formulation showed superior potency and avoidance of immune stimulation relative to others.
- Genevant LNP technology is included in the first RNA-LNP product to receive FDA-approval, Alnylam’s Onpatro (patisiran).

• **IP litigation:**

- In February 2022, Genevant and Arbutus jointly filed a complaint against Moderna in the U.S. District Court for the District of Delaware asserting infringement of six patents. In April 2024, the court in the Moderna case issued its claim construction (Markman) ruling, in which it agreed with Genevant and Arbutus' proposed constructions for three of the four disputed terms. The court is expected to entertain requests to file summary judgment motions in late calendar year 2024 and a trial date has been set for April 2025.
- In April 2023, Genevant and Arbutus jointly filed a complaint against Pfizer and BioNTech in the U.S. District Court for the District of New Jersey asserting infringement of five patents. The case is ongoing and a date for a claim construction (Markman) hearing has not been set.

• **Roivant ownership:**

- As of March 31, 2024, we own 83% of the issued and outstanding common shares of Genevant and 65% on a fully diluted basis.

Asset Acquisition and License Agreements; Other Vant Agreements

Dermavant

GSK and Welichem Agreements; Thermo Fisher Agreement

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 VTAMA 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 VTAMA 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. The GSK Agreement does not require DSG to pay any royalties on sales of VTAMA following commercialization or make any commercial milestone payments, except for milestones owed to Welichem as described below.

Following the FDA approval of VTAMA in May 2022, DSG became obligated to pay a regulatory milestone to GSK of £100.0 million (approximately \$126.0 million on the date of achievement) following the receipt of marketing approval of VTAMA in the U.S. The milestone was paid in July 2022. Additionally, the first sale of VTAMA in May 2022 resulted in the achievement of a milestone to Welichem of CAD\$25.0 million (approximately \$20.0 million on the date of achievement). The milestone was paid in August 2022.

In addition, under the GSK Agreement, DSG assumed all obligations under the Welichem Agreement, including initially up to CAD\$180.0 million in potential development and commercial milestone payments, of which CAD\$105.0 million have been achieved and paid as of March 31, 2024.

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 (the "Clinical Supply Agreement") for VTAMA pursuant to which DSG obtained an existing supply of VTAMA drug product and drug substance as well as additional supply of VTAMA drug product for clinical trials on a cost plus basis. As required under the GSK Agreement, in April 2019, DSG entered into a commercial manufacturing and supply agreement (the "Commercial Supply Agreement") with GSK Trading to continue to provide certain quantities of VTAMA drug product and drug substance at agreed upon minimum quantities and price. The Commercial Supply Agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, DSG and GSK entered into a Partial Termination and Supplementary Fee Agreement relating to the Clinical Supply Agreement and Commercial Supply Agreement, which amended the terms of the Clinical Supply Agreement and the Commercial Supply Agreement (the "GSK Amendment"). The GSK Amendment released GSK Trading from certain commitments to supply VTAMA and released DSG from certain commitments to purchase VTAMA in exchange for a supplementary fee. Other supply and purchase commitments under the Clinical Supply Agreement and the Commercial Supply Agreement remain in effect and were not impacted by the GSK Amendment.

In addition, in July 2022, DSG and Thermo Fisher Scientific ("TFS") entered into a Master Commercial Manufacturing and Supply Agreement, under which TFS will provide a supply of VTAMA to DSG at an agreed upon price.

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, DSG has received (i) an upfront payment of \$60.0 million in January 2020 and (ii) payments of \$10.0 million and \$15.0 million in December 2021 and September 2023, respectively, related to development milestones that were achieved, and DSG may receive up to an additional \$28.0 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 entered into between the parties in February 2024. 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 sublicensees participate in a challenge to certain of our patents.

Dermavant Financing Agreements—Funding Agreement with NovaQuest

In connection with Dermavant's acquisition of tapinarof from GSK pursuant to the GSK Agreement, Dermavant and NovaQuest Co-Investment Fund VIII, L.P., an affiliate of NovaQuest Capital Management, LLC ("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 the \$117.5 million in total funding from NovaQuest, Dermavant agreed to make fixed payments to NovaQuest under the NovaQuest Agreement upon regulatory approval of tapinarof. For each of the atopic dermatitis and psoriasis indications, Dermavant is required to make quarterly payments to NovaQuest totaling \$176.3 million per indication over a six-year period following regulatory approval of tapinarof for the applicable indication in the U.S. In the event that Dermavant receives regulatory approval for one indication, and Dermavant terminates the development of the other indication for any reason other than a Technical Failure (as defined below), then Dermavant will be required to make the above-referenced quarterly payments to NovaQuest up to \$440.6 million over a 15-year period for the approved indication (the "15-Year Payments"). A Technical Failure is deemed to occur for an indication if the development program for such indication is terminated due to (1) significant safety concerns, (2) material adverse developments or (3) the receipt by Dermavant of a complete response letter or a final non-approval letter from the FDA is expected to result in significant delay or cost to reach commercialization for the applicable indication. In addition, Dermavant is required to make up to \$141.0 million in payments to NovaQuest upon achievement of certain commercial milestones. In the event that Dermavant is required to start making the 15-Year Payments, then Dermavant has the right to offset such amounts by up to \$88.1 million of the commercial milestone payments, with such offset being applied to the quarterly payments in reverse chronological order (such that the final quarterly payments owed will be used first to offset the commercial milestone payments). The NovaQuest Agreement does not contain any royalty payment requirements on commercialization of tapinarof. Upon receiving FDA approval for the psoriasis indication, Dermavant made its first quarterly payment of \$7.3 million under the NovaQuest Agreement in May 2022 and has made cumulative quarterly payments totaling \$58.8 million as of March 31, 2024.

In May 2024, Dermavant entered into an amendment to the NovaQuest Agreement as part of a renegotiation of its existing debt obligations. For more information, see "Item 9B. Other Information."

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, 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.

In June 2022, following satisfaction of the funding conditions set forth in the RIPSA, including receipt of marketing approval from the FDA for VTAMA (received in May 2022), the Purchasers paid 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 has 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 VTAMA in the U.S., up to a cap of \$344.0 million. Payments of such quarterly revenues to the Purchasers under the RIPSA are secured by a security interest in certain VTAMA-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 VTAMA.

The RIPSAs contain certain representations and warranties and covenants applicable to DSL and its subsidiaries. The RIPSAs also contain certain Events of Default (as defined in the RIPSAs) 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 RIPSAs) of \$160.0 million, less revenue payments previously paid, as liquidated damages.

In May 2024, Dermavant entered into an amendment to the RIPSAs as part of a renegotiation of its existing debt obligations. For more information, see "Item 9B. Other Information."

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 a then-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, until 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 in 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 RIPSAs, has received cumulative payments from DSG under the RIPSAs 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).

In May 2024, Dermavant entered into an amendment to the Credit Agreement as part of a renegotiation of its existing debt obligations. For more information, see "Item 9B. Other Information."

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 (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to (a) develop, import and use (i) the antibody referred to as batoclimab, (ii) certain back-up and next-generation antibodies (including IMVT-1402), and (iii) products containing such antibodies, and (b) to commercialize such products, in the U.S., 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: (1) a third party in any country in the HanAll Licensed Territory outside of the U.S. and E.U.; (2) an affiliate of RSG in any country in the HanAll Licensed Territory; and (3) a third party in the U.S. and E.U. only after submission of a Biologics License Application (“BLA”) in the U.S. 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 controlled by RSG relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the HanAll Licensed Territory. HanAll also reserves the right to conduct discovery or research activities with the batoclimab antibody, and certain back-up and next-generation antibodies (including IMVT-1402), with or through a contract research organization or service provider in 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-1402 and batoclimab in the HanAll Licensed Territory, for an aggregate purchase price of \$37.8 million.

Pursuant to the HanAll Agreement, ISG was obligated to reimburse HanAll for half of certain specified research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of \$20.0 million, which obligation has since expired. As of March 31, 2024 and 2023, ISG did not have any additional amounts payable to HanAll for research and development costs incurred and reported to it pursuant to the HanAll Agreement.

During the quarter ended June 30, 2023, ISG achieved its third and fourth development and regulatory milestones under the HanAll Agreement of \$12.5 million, combined, which was paid during the quarter ended September 30, 2023. ISG will be responsible for future contingent payments and royalties, including up to an aggregate of \$420.0 million (after an aggregate amount of \$32.5 million paid for milestone events achieved as of March 31, 2024) upon the achievement of certain regulatory and sales milestone events. ISG is also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens percentage of 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: (A) the date on which the last valid claim of the licensed patents expire, (B) the date on which the data or market exclusivity expires or (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

Except for cost-sharing in connection with the research program, ISG is solely responsible, at its expense, for all other activities related to the research, development and commercialization of licensed products for the HanAll Licensed Territory. ISG may use a third party for manufacturing activities necessary for the research, development and commercialization of licensed products for the HanAll Licensed Territory. In addition, under the HanAll Agreement, ISG has agreed to use commercially reasonable efforts to develop and commercialize licensed products in the HanAll Licensed Territory. Each party has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

Under the HanAll Agreement, ISG has the sole right, but not the obligation, to control the prosecution, defense and enforcement of the licensed patents in the HanAll Licensed Territory, and HanAll has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which ISG elects not to exercise such rights.

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.

Product Service Agreement and Master Services Agreement

On November 17, 2021, ISG entered into a Product Service Agreement (“PSA”) with Samsung Biologics Co., Ltd. (“Samsung”), pursuant to which Samsung will manufacture and supply ISG with batoclimab drug substance for commercial sale, if approved, and perform other manufacturing-related services with respect to batoclimab. ISG previously entered in a Master Services Agreement (“MSA”) with Samsung, dated April 30, 2021, which governs certain terms of its relationship with Samsung. Upon execution of the PSA, ISG committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition to these, since ISG did not exercise an early termination right prior to its expiration in January 2024, ISG has an additional minimum obligation to purchase additional batches of batoclimab in the four-year period of 2026 through 2029.

The PSA will continue until the later of December 31, 2029 or the completion of the services thereunder, unless the PSA is terminated earlier. Either party may terminate the PSA on account of (i) the other party's material breach of the PSA that is not cured within a specified period after the termination notice, (ii) the other party's insolvency or bankruptcy or (iii) certain force majeure events. The remaining minimum purchase commitment related to this agreement was estimated to be approximately \$46.2 million as of March 31, 2024.

Priovant

License and Collaboration Agreement with Pfizer, Inc.

In September 2021, our subsidiary Priovant Therapeutics, Inc. ("Priovant") entered into a license and collaboration agreement with Pfizer (the "Pfizer-Priovant License Agreement"). Pursuant to the Pfizer-Priovant License Agreement, Pfizer granted Priovant (i) an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and (ii) a non-exclusive, worldwide, sublicensable, royalty-bearing license under certain know-how, in each case, to develop, manufacture and commercialize brepocitinib and TYK2 compounds and products incorporating such compounds for all human and animal uses. In exchange for Pfizer's inventory of these compounds, Priovant paid Pfizer \$10.0 million. Priovant also granted back to Pfizer (i) an exclusive, sublicensable, royalty-bearing license under certain patents and (ii) a non-exclusive, sublicensable, royalty-bearing license under certain know-how, in each case, to commercialize (x) brepocitinib and products incorporating such compound outside of the U.S. and Japan, and (y) TYK2 compounds and products incorporating such compound outside of the U.S., in each case for all human and animal uses.

Priovant is obligated to pay Pfizer a mid tens-of-millions sales milestone payment if aggregate net sales of its licensed products in Priovant's territory in a given year exceed a mid hundreds-of-millions amount. Pfizer is obligated to pay Priovant a low tens-of-millions milestone payment if aggregate net sales of its licensed products outside of Priovant's territory in a given year exceed a mid hundreds-of-millions amount.

Priovant is obligated to pay Pfizer a tiered, sub-teens royalty on aggregate net sales of its licensed products in Priovant's territory. Pfizer is obligated to pay Priovant a tiered high single-digit to sub-teens royalty on aggregate net sales of its licensed products outside of Priovant's territory. Each of Priovant's and Pfizer's royalty obligations apply on a product-by-product and country-by-country basis and end upon the expiration of a customary royalty term, which is the latest of (a) a certain amount of years following the first commercial sale of the applicable products in the applicable country, (b) the date on which the regulatory exclusivity provided by the applicable government authority for the applicable products in that country expires and (c) the date upon which the use, sale, offer for sale or importation of such product in such country would no longer be covered by a valid claim of a licensed product right. Either party may terminate for the other party's uncured breach and Priovant has the right to terminate for convenience.

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 GalNAc 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 been 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 a 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 begin to expire as early as 2023, ending 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 sales related 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.

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 U.S. 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

Dermavant

As of March 31, 2024, DSG is the exclusive owner of patent families that include 13 issued U.S. patents and 8 pending U.S. and Patent Cooperation Treaty (“PCT”) patent applications, as well as 99 issued patents and more than 72 pending patent applications in other jurisdictions, including the European Union and Japan, relating to VTAMA, the synthesis of VTAMA, intermediates made in the synthesis, the drug substance crystal form, topical formulations of VTAMA and uses thereof in certain diseases and disorders.

One of these patent families is directed to the topical formulation of VTAMA, and its use to treat plaque psoriasis, for which VTAMA has received FDA approval, as well as its use to treat atopic dermatitis, which has been evaluated in Phase 3 clinical trials, which includes a family of patents and patent applications in the U.S. and major foreign jurisdictions that has a natural expiration date in 2036, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. Within this patent family, we have issued four formulation patents in the U.S. with claims directed to topical, homogeneous, oil-in-water micro-emulsions, including VTAMA, containing tapinarof (the active ingredient in VTAMA), an oil phase, a surfactant and other specific ingredients. DSG also owns two issued patents in the U.S. covering methods of using the patented formulations to treat inflammatory diseases, including psoriasis and atopic dermatitis. Like the formulation patents, the method-of-use patents have a natural expiration date in 2036 in the U.S., without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Foreign counterpart formulation and method-of-use patents are both issued and pending, and the issued counterparts also have a natural expiration date in 2036, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

DSG also owns two drug substance (“DS”) patents in the U.S. covering the high purity crystal form of VTAMA, as DS, the DS synthesis and several novel intermediates that are formed in the synthesis. The DS patents have a natural expiration date in 2038 assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees and without taking into account any possible patent term adjustments or extensions. DSG has also filed foreign counterpart DS applications that are both issued and pending in foreign jurisdictions and the issued counterparts similarly have a natural expiration date in 2038, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. DSG also owns a method-of-use patent in the U.S. covering the method of treating mild to severe plaque psoriasis by topically administering VTAMA to achieve treatment success as measured by psoriasis PGA scores. This patent expires in 2039, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Finally, DSG owns two method-of-use patents in the U.S. covering the method of treating mild to severe atopic dermatitis by topically administering VTAMA to achieve treatment success as measured by psoriasis IGA scores. These patents expire in 2039 assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees and without taking into account any possible patent term adjustments or extensions.

Anti-FcRn Franchise

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 certain patents, patent applications and know-how directed to batoclimab, IMVT-1402 and certain back-up and next-generation antibodies, and products containing such antibodies, in the HanAll Licensed Territory. As of May 22, 2024, the in-licensed patent portfolio includes a patent family covering batoclimab with pending patent applications and/or issued patent(s) in the U.S., Argentina, Brazil, Canada, Colombia, European Patent Office, Egypt, Israel, Mexico and Saudi Arabia. This in-licensed patent family was filed in 2015 and discloses anti-FcRn antibodies, including batoclimab, 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. Notably, in this in-licensed patent family, a U.S. patent was issued on July 2, 2019, with claims directed to batoclimab as defined by its CDRs and epitope or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof. Furthermore, another U.S. patent was issued in this in-licensed patent family on January 28, 2020, with claims directed to batoclimab as defined by its CDRs or antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of producing such antibody or antigen-binding fragment. A further patent was issued in the U.S. on March 28, 2023 with claims to an isolated anti-FcRn antibody other than batoclimab or an antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. A European patent in this family was issued on May 10, 2023 with claims directed to batoclimab as defined by its heavy and light chain variable sequences. There are also issued patents in this family in Brazil, Canada, Israel, Mexico, and Saudi Arabia. In this family, applications are pending in Argentina, Mexico, the U.S. and in Europe. The patents of this patent family may expire in 2035, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

In addition, the in-licensed patent portfolio includes another patent family that discloses a pharmaceutical formulation for an anti-FcRn antibody. This patent family includes pending applications in the U.S., and in Europe, Israel, Canada, Brazil, Mexico and Argentina, and any patent issued in this patent family may expire in 2041, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Additionally, as of May 22, 2024, independent of the licensed patent portfolio, ISG owns patent families directed to methods of treating thyroid eye disease (Graves' ophthalmopathy) and methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies that include patent applications in the U.S. as well as foreign counterparts in certain jurisdictions. Any patent issued from these patent families may expire in 2039 and 2040, respectively, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

ISG jointly owns rights with HanAll to a patent family covering IMVT-1402 and its uses to treat autoimmune disease. A PCT application is pending in this family. Notably, in this patent family, a U.S. patent was issued on March 12, 2024, with claims directed to IMVT-1402 as defined by its CDRs, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, and methods of treating an autoimmune disease using such antibody or antigen-binding fragment thereof. The patents of this patent family may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

ISG also owns PCT applications directed to methods of treating Graves' Disease and methods of treating Chronic Inflammatory Demyelinating Polyneuropathy using anti-FcRn antibodies including IMVT-1402 and batoclimab. Any patent issued from these patent families may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

ISG also owns a PCT application directed to high concentration protein formulations with polysorbate excipients and methods of making the same. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

ISG also owns a U.S. provisional application directed to methods of improving anti-FcRn therapies, which describes specific dosing regimens for IMVT-1402. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension 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."

Priovant

As of March 31, 2024, Priovant Therapeutics, Inc. has (1) exclusively licensed rights to six patent families for brepocitinib containing at least 172 issued patents and 65 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering a composition of matter, a crystalline form, a topical formulation, a process for making brepocitinib, a treatment of hidradenitis, a dosage regimen for treatment of hidradenitis and treatment of dermatomyositis with brepocitinib. 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, and (2) exclusively licensed rights to three patent families for ropsacitinib containing at least 126 issued patents and 25 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering a composition of matter, a treatment of hidradenitis and a crystalline form. These patents and pending applications, if issued, are expected to expire as early as 2037, 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.

Genevant

As of March 31, 2024, we own or co-own 19 patent families containing 38 issued patents and 111 pending patent applications in the U.S., European Union and numerous other jurisdictions, including claims relating to lipid nanoparticle delivery technology, polymers and nucleic acid delivery constructs. These patents and pending applications, if issued, are expected to expire between 2029 and 2044, 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 March 31, 2024, we have licensed 35 patent families containing 481 issued patents and 269 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 July 2024 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.

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 U.S. 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, 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 U.S., 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 U.S. 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 U.S.

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 or biological product 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 nonclinical (e.g., 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.

A sponsor who wishes to conduct a clinical trial outside of the U.S. 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 March 2022, the FDA finalized a guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” the draft of which was released in August 2018. This final guidance 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 early 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 U.S.

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 significantly curtailed its inspection program. The reduction in pre-approval inspections resulted in delays to some product approvals. Even with the mostly complete resumption of the FDA's normal inspection program and continued use of alternative inspection tools, there may be delays to product approvals in the future based on a resurgence of, or new problems with respect to the FDA's ability to conduct inspections and then, even after a complete 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 U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. 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 or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the U.S. or affects more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. 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 rare pediatric disease 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 an NDA 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 NDA 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. FDA may require such trials to be underway prior to, or within a specific period after, approval and will specify the conditions for such studies. Further, sponsors must provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed. The failure to conduct required post-approval clinical trials with due diligence and the failure to submit the required reports are prohibited acts. 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 is not conducted or fails to verify the predicted clinical benefit of the product. FDA can withdraw accelerated approvals on an expedited basis provided certain procedures are followed.

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.

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 and breakthrough therapy 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 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 U.S. 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;
- 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, typically 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 U.S., 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 other predicate devices, 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 will transition to the Quality Management System Regulation once effective and 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 QSR, 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 suggested 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 September 2023, FDA announced a proposed rule, which was published in October 2023, to revise the regulatory definition of an *in vitro* diagnostic product to explicitly capture laboratory developed tests and make clear that such tests are medical devices subject to FDA regulation. The proposed rule also described a proposed policy under which FDA will gradually end its general enforcement discretion policy for laboratory developed tests in phases over a four-year period. Although FDA and other stakeholders would have preferred a legislative solution to the regulation of laboratory developed tests, we anticipate that FDA will attempt to issue the final rule this year.

Biosimilars and Exclusivity

Certain of our product candidates, including batoclimab, 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 PHS Act, 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 U.S. 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 U.S. 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 making clinically-appropriate decisions enabling patient access to 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 U.S., these laws include: the federal Anti-Kickback Statute, the False Claims Act and the Health Insurance Portability and Accountability Act ("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, which would preclude reimbursement of our products under the Medicare and Medicaid 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 FDA regulations for the protection of human research subjects require that we protect the privacy of personal information and obtain appropriate informed consent in connection with research using identifiable subject information or identifiable biological samples. In addition, the data privacy and security regulations implementing HIPAA impose strict limitations on the use and disclosure of individually identifiable health information, including for research purposes. 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, the Federal Trade Commission has broad authority to investigate and initiate enforcement actions regarding any activity affecting the privacy or security of personal information that it deems deceptive or unfair. At the state level, a rapidly growing body of privacy and data protection laws impose requirements and restrictions, some of which are more stringent than federal law and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties.

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 were extended 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 U.S. 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 U.S. 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, there are ongoing challenges in federal court and 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 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 and/or Congress. For example, a rule enacted under the Trump Administration known as the "Most Favored Nations" rule would have 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 was the subject of litigation and was formally rescinded by 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, which took effect on January 1, 2020.

Other legislative changes have been proposed and adopted in the U.S. 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 the first six months of 2032 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. There was a 1% reduction through the end of June 2022, after which the cuts returned to 2%. Absent further Congressional action, there is a possibility that an up to 4% Medicare sequester could be triggered in January 2025, pursuant to the Statutory Pay-As-You-Go Act of 2010 ("PAYGO"). Under PAYGO, if the five- or ten-year PAYGO scorecard shows a net cost at the end of a Congressional session, then the Office of Management and Budget is required to issue a sequestration order. The American Rescue Plan Act of 2021 was expected to trigger a PAYGO sequestration order at the end of the 2021 Congressional session. However, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024. Additionally, the American Rescue Plan Act of 2021 eliminated the Medicaid unit rebate AMP cap effective as of January 1, 2024, and the removal of this rebate cap could significantly impact our Medicaid rebate liability in the future.

There has been increasing legislative and enforcement interest in the U.S. 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. 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. In August 2022, Congress enacted the Inflation Reduction Act ("IRA"), a law that included sweeping changes to the payment for drugs under the Medicare program. Among other provisions, the IRA contains (i) a drug price negotiation program for certain high spend Medicare drugs that have been on the market for a certain length of time and lack generic or biosimilar competition, under which Medicare prices for such drugs are capped by a "maximum fair price"; (ii) new manufacturer rebate obligations on certain drugs paid under Medicare Part B or D whose prices increase faster than inflation relative to a benchmark period; and (iii) a redesign of the Part D benefit, including capping patients' annual out-of-pocket costs on Part D drugs, lowering the beneficiary out-of-pocket threshold, streamlining the Part D benefit to eliminate the "coverage gap" phase, and replacing the manufacturer coverage gap discount program with a new manufacturer discount program – the Medicare Part D Manufacturer Discount Program – that provides discounts throughout the post-deductible benefit phases. CMS has begun to implement certain aspects of the IRA, including issuing final guidance describing drug negotiation, inflationary rebates and Part D redesign and selecting Part D drugs for the initial rounds of negotiation, which ultimately will result in the establishment of maximum fair prices, which would become effective in 2026. In November 2023, CMS released final guidance on the Medicare Part D Manufacturer Discount Program implementing exceptions for "specified manufacturers" and "specified small manufacturers," which allows for a phase-in of discounts under the program. Although CMS did not find Dermavant eligible for these exceptions (presumably because sales of VTAMA did not begin until 2022, following its FDA approval in May 2022), we cannot predict how these exceptions may impact other aspects of Roivant's business in the future. Over time, provisions of the IRA could increase our government discount and rebate liabilities, reduce the revenues we are able to collect from sales of our products as well as present challenges for payor negotiations and formulary access. However, the degree of impact that the IRA will ultimately have upon our business remains unclear at this time.

In October 2022, President Biden issued an executive order calling on the Secretary to consider whether to select for testing by the CMS innovation center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. In response, the CMS innovation center released a report in February 2023, identifying three selected models: Medicare High-Value Drug Model, the Cell & Gene Therapy Access Model, and the Accelerating Clinical Evidence Model. We cannot predict how these new provisions would be implemented or the impact they will have on our business.

It is possible that Congress or the Administration may take further actions to control drug prices. Further federal, state and foreign legislative and regulatory developments are likely, and we expect these already enacted and 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. In particular, the obligation to provide notices of price increases to purchasers under laws such as California's SB-17 may influence customer ordering patterns for our products, which in turn may increase the volatility of our revenues as a reflection of changes in inventory volumes. In addition, some state legislatures have established Prescription Drug Affordability Boards ("PDABs"), which under certain circumstances may conduct affordability reviews and establish upper payment limits for drugs purchased in the state. On August 4, 2023, the Colorado PDAB commenced an affordability review of five prescription drugs, including three products that are indicated to treat plaque psoriasis (ENBREL®, COSENTYX®, STELARA®). We cannot predict the outcome of this affordability review, whether the Colorado PDAB will establish upper payment limits for one or more of these drugs, or the impact of any such upper payment limit on utilization of VTAMA. We may continue to see additional state action related to prescription drug pricing.

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, diversion or misuse 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 products, 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 U.S. 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

On June 23, 2016, the electorate in the U.K. 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 U.K. 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 U.K. However, this ended on December 31, 2020. On December 30, 2020, the U.K. and European Union signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties. Further, on February 27, 2023, an agreement in principle was reached by the UK and EU (the "Windsor Agreement"), relating to post-Brexit trade issues in Northern Ireland, which if implemented into the respective legislation, seeks to simplify the supply of medicines between Great Britain and Northern Ireland and will mean the EU legislation may not apply in all cases in Northern Ireland. Since the regulatory framework in the U.K. 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 U.K., 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 U.K. 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 U.K.'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.

In the EEA, which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, and in the U.K., our future products also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the relevant competent authority has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in the EEA and U.K. are subject to significant regulatory controls. The EU Clinical Trials Directive 2001/20/EC (the "Directive") 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 this 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 this 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 is undergoing a transition process due to the application of a new Clinical Trials Regulation (EU) No 536/2014 (the "Regulation"), which is 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 the Regulation, which started to apply on January 31, 2022 and replaced the current Directive. Specifically, the new Regulation, which is 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. It also provides for increased transparency and proactive publication of clinical trial documents and results, subject to certain exceptions and derogations.

Following Brexit, this Regulation is not applicable in the UK, and the national legislation put in place to implement the Directive continues to apply to trials conducted in the UK.

European Union and United Kingdom Drug Marketing

Much like the federal Anti-Kickback Statute prohibition in the U.S., the provision of benefits or advantages to physicians and/or healthcare organizations to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, administration or use of medicinal products is also prohibited in the EEA and U.K. EU Directive 2001/83/EC, which is the Directive governing medicinal products for human use, as implemented in the relevant Member State and the UK, 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, collectively govern the provision of benefits or advantages to induce or reward improper performance. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC 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 UK 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 EEA 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 EEA, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). There are two main types of marketing authorizations for innovative medicinal products, which, however, are based on largely identical regulatory rules, requirements and timelines, including the 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.
- 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 U.K. (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain is no longer covered by centralized MAs (under the Northern Irish Protocol of the Withdrawal Agreement, centralized MAs will continue to apply in Northern Ireland, although this may change if the Windsor Agreement is implemented). All medicinal products with a valid centralized MA as of December 31, 2020 were automatically converted to MAs valid in Great Britain on January, 1 2021 (unless the MA holder opted out of this procedure). On January 1, 2024, the International Recognition Procedure (“IRP”) was introduced, whereby the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the UK medicines regulator, may rely on a decision taken by other international regulators, including the European Commission and the U.S. FDA, in order to more quickly grant a new MA valid in Great Britain or the U.K. A separate application will, however, still be required and the MHRA has the right to undertake its own assessment of the dossier. There are two such routes, allowing recognition in a 60-day or 110-day timelines. The IRP is in addition to the MHRA’s national procedures, including the shortened 150-day timetable.

European Union and United Kingdom Data Protection and Market 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 protection upon marketing authorization and an additional two years of market exclusivity. The data protection, if granted, prevents generic or biosimilar applicants from referencing the innovator’s preclinical 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 protection, 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 European Commission, based on the scientific assessment from 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 benefits such as scientific advice (protocol assistance) and 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.

On April 26, 2023, as part of the EU Pharmaceutical Strategy, the European Commission published a proposal for a comprehensive revision of the EU pharmaceutical legislation. If adopted by the European Parliament and the Council, the new legislation is likely to significantly change the regulatory regime applicable to both (i) the “non-orphan” data protection and market exclusivity regime described in the previous section; and (ii) the orphan exclusivities. Subject to the outcome of the ongoing legislative process in the European Parliament and the Council, the revisions may potentially reduce/modulate the rewards that could be granted to both non-orphan and orphan medicinal products. In addition, the proposal envisages changes to the concept of unmet medical need and considers introducing novel rewards for orphan medicinal products addressing high unmet medical need. The adoption of the new legislation is not expected before 2025 and it will start to apply 18 months after the entry in force.

From January 1, 2021, a separate process for orphan drug designation has applied in Great Britain. There is no pre-marketing authorization orphan designation step required (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 (although this may change if the Windsor Agreement is implemented).

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.

As noted above, the upcoming legislative reforms in the EU, which are part of the new EU Pharmaceutical Strategy may potentially result in a reduction of the above pediatric rewards and/or imposition of additional requirements for grant of rewards.

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 U.S. 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”). In July 2023, the U.S. and EU implemented the EU-U.S. Data Privacy Framework (“DPF”) replacing the invalidated Privacy Shield. Companies can now use this new mechanism to transfer personal data from the EU to the U.S. and potentially from Switzerland to the U.S., subject to national implementation in Switzerland. The UK Extension to the EU-U.S. Data Privacy Framework (“Data Bridge”) entered into force in October 2023, allowing certifying entities to transfer personal data from the UK to the U.S. At the moment it is unclear whether the anticipated legal challenges against the DPF, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful.

In July 2020, the CJEU upheld the validity of standard contractual clauses (“SCCs”) as a legal mechanism to transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection and in July 2021, the European Commission adopted new SCCs. Even so, companies relying on SCCs must, subject to additional guidance from regulators in the EEA and the U.K., regularly evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs.

The use of the new SCCs may increase the legal risks and liabilities under EEA privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs and the DPF, any transfers by us or our vendors of personal information from the EEA to the US may not comply with the EEA data protection laws, which may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of EEA personal information outside of the EEA (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products.

The competent authorities and courts in a number of EU Member States continue to closely scrutinize and question the GDPR compliance of processing of personal data by US-based entities or entities with links to US-based entities, independently of whether personal data is actually transferred outside the EEA. 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 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.

In addition, further to the U.K.'s exit from the European Union on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'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 U.K.'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 U.K., 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 adequacy decision will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or unilaterally revoked in the interim at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. On March 8, 2024, the British Government published the Data Protection and Digital Information (No.2) Bill intended to create a more business friendly regime in the UK through changes to the existing legislation. At this stage it is unclear whether and when this legislation will be adopted and whether such legislative reforms could potentially lead the European Commission not to extend or to revoke the UK adequacy decision.

Rest of the World Regulation

For other countries outside of the European Union and the U.S., 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 U.S., 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 U.S. 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 U.S., 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 U.S., 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 U.S., 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 programs, such as Medicare and Medicaid, 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, and efforts of third-party payors to contain or reduce health care costs may adversely affect our ability to establish or maintain appropriate prices for our products or any drugs that we may develop and commercialize. Such efforts include the use of accumulator adjustment programs that do not consider amounts paid by pharmaceutical copay assistance programs as counting towards a patient's deductible or other out-of-pocket costs. Under new rules promulgated by CMS that would have taken effect January 1, 2023, such accumulator adjustment (or similar) programs could affect the amount of rebates owed by manufacturers under the Medicaid Drug Rebate Program or affect our ability to offer various forms of patient support, including copay assistance. However, this regulation was struck down in Federal court in May 2022. Additionally, in May 2023, CMS issued a new proposed rulemaking that would repeal the changes implemented by the court-vacated December 2020 final rule regarding co-payment assistance programs. Additionally, there was litigation challenging CMS' co-pay accumulator policies for non-grandfathered health plans. On September 29, 2023, a federal district court vacated provisions of the 2021 Notice of Benefit and Payment Parameter ("NBPP") final rule that provided health plans with discretion whether to include manufacturer assistance toward the annual cost-sharing limit. Further, on December 22, 2023, the district court clarified that the effect of the vacatur is to reinstate the 2020 NBPP final rule, which barred the use of accumulators for brand drugs without generics. Both parties initially appealed, and subsequently withdrew their appeals. In its 2025 NBPP final rule, CMS did not address its co-pay accumulator policy and has not issued other guidance explaining its interpretation of the court's ruling, including whether the 2020 NBPP rule will be enforced. At the same time, however, certain states have passed laws prohibiting third-party payors from utilizing accumulator programs.

Government authorities and third-party payors also 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 U.S. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the U.S., the acquisition costs and reimbursement for drug products may be lower than within the U.S.

In the U.S., 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.

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. 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 (“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.

Many parameters of the 340B program are subject to uncertainty. Several drug manufacturers have commenced litigation, which remains ongoing, challenging the legality of contract pharmacy arrangements, which may affect the way in which manufacturers are required to extend the 340B Drug Discount Program prices to covered entities, including through contract pharmacies. Manufacturers also challenged the implementation of the 340B Administrative Dispute Resolution Process, which is in part intended to resolve claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers. In November 2022, the Health Resources and Services Administration (“HRSA”) issued a proposed rule to amend its administrative dispute resolution process for certain disputes arising under the 340B drug pricing program. The public comment period closed on January 30, 2023. The nature of the Administrative Dispute Resolution Process, once finalized, may impact on our revenue. Additionally, although HRSA historically has interpreted 340B discounts to apply only to “patients” who had their care initiated at a given 340B covered entity, a November 2023 district court ruling struck down this understanding as too narrow. Although the ruling applies only to the parties to the litigation, it introduces uncertainty as to the scope of the 340B program and may serve as a precedent for future litigation or legislation impacting the industry at large. In another ongoing case impacting the scope of the 340B program, in November 2023, various hospitals sued HRSA to challenge an agency policy requiring that “child sites” of a hospital must be included on that hospital’s most recent Medicare cost report to qualify for discounts under the program. The outcome of this litigation could increase the speed at which new locations of 340B covered entities are able to access 340B discounts. Finally, it also is possible that Congress could consider other legislation that amends or reforms the 340B Drug Discount Program.

Moreover, there also is significant uncertainty related to the insurance coverage and reimbursement of cell or genetic therapy products. Although a new rule finalized by CMS for the Medicaid Drug Rebate Program increased flexibility regarding the manner in which manufacturers may offer value-based discounting arrangements, and following a regulatory delay, took effect on July 1, 2022.

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 U.S., 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 March 31, 2024, we and our subsidiaries had approximately 908 full-time employees, including 845 in the U.S.

Our human capital objectives include sourcing, recruiting, retaining, incentivizing and developing our existing and future employees. We believe we can achieve our human capital objectives by implementing the following approaches:

- Hire high-caliber talent across all levels using both a dedicated in-house talent acquisition team and top-tier executive search firms
- Recruit diverse, multidisciplinary talent from a broad range of industries, including biopharmaceuticals, financial services, technology, and consulting
- Invest in early career diversity through a robust Rotational Analyst (RA) program, hiring recent college graduates from top private and public institutions
- Support Roivant/Roivant Social Ventures' Diversity in Pharma summer internship program for current PharmD candidates
- Offer highly competitive short- and long-term incentives through both Roivant and Vant equity programs and meaningful performance-based cash bonuses
- Undertake rigorous benchmarking analyses in partnership with third parties to ensure competitive compensation practices and conduct annual pay equity analyses to detect, analyze, and remediate any compensation disparities where appropriate
- Provide company-wide training and speaker programs on topics such as unconscious bias and professional development
- Partner with external organizations to support biopharma-related initiatives in the community
- Offer a professional development stipend to each employee for use towards individual growth and development
- Unlock unique career progression across Roivant and Vants through "Vant mobility" and offer unparalleled leadership opportunities for employees through the Vant model
- Cultivate diversity and inclusion among our employee base through Employee Resource Groups (ERGs), including Women@Roivant (Roivant's women's employee resource group), ROI-GBIV (Roivant's LGBTQ+ employee resource group), and BIPOC (Roivant's black, indigenous and people of color employee resource group)

In addition to these specific recruitment and retention practices above, we believe the Vant model offers significant human capital advantages. Our nimble, entrepreneurial Vants operate similarly 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. As a public company, we expect to continue 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 7th Floor, 50 Broadway, London SW1H 0DB, 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. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov. 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.

ITEM 1A. 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 Annual Report on Form 10-K, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and the related notes, 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. Unless the context otherwise requires, references in this section to “we,” “us,” “our,” “Roivant” and the “Company” refer to Roivant Sciences Ltd. and its subsidiaries and affiliates, as the context requires.

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 and commercialization may make it difficult for us to execute on our business model and for you to assess our future viability. We have generated limited revenue from our operations since inception, and there is no guarantee that we will generate significant revenues in the future.

We are a commercial-stage 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 primarily been limited to acquiring or in-licensing product candidates, pursuing the clinical development and commercialization of those product candidates, efforts to discover new product candidates, financing activities and the creation or acquisition of healthcare technology companies and products, as well as the oversight and management of our subsidiaries developing and commercializing medicines, which we refer to as “Vants.”

Following the approval by the U.S. Food and Drug Administration (the “FDA”) in May 2022 of VTAMA® (tapinarof) cream, 1%, for the treatment of adults with plaque psoriasis, we commenced our transition from a clinical-stage company to one with commercial-stage assets. In February 2024, we submitted a Supplemental New Drug Application (“sNDA”) to the FDA for VTAMA for the topical treatment of atopic dermatitis (“AD”) in adults and children 2 years of age and older. VTAMA is not currently approved in any other jurisdictions and we do not have any other product candidates that have received regulatory approvals in the U.S. or in any other jurisdiction.

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

- successfully continue to commercialize VTAMA;
- successfully complete ongoing preclinical studies and clinical trials and obtain regulatory approvals for our current and future product candidates;
- identify new acquisition or in-licensing opportunities;
- launch commercial sales of future product candidates, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- successfully grow our healthcare technology Vants and market the products and services offered by those Vants;
- attract and retain experienced management and advisory teams;
- add operational, financial and management information systems and personnel, including personnel to support clinical, preclinical manufacturing and commercialization efforts and operations;
- initiate and maintain relationships with third-party suppliers and manufacturers and have commercial quantities of products and product candidates manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;

- set acceptable prices for products and product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of products and product candidates in the medical community and with third-party payors and consumers;
- raise additional funds when needed and on terms acceptable to us;
- successfully identify new product candidates through our discovery efforts and advance those product candidates into preclinical studies and clinical trials; and
- maintain, expand and protect our intellectual property portfolio.

If we cannot successfully execute on these objectives, our business may not succeed and the price of our common shares may be negatively impacted.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict when and if our products and product candidates will achieve various milestones in their clinical development, including marketing approval from the FDA or other regulatory authorities, the timing or amount of increased expenses related to these activities or when we will be able to generate significant revenues or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or other 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 in the U.S. or another jurisdiction, 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. We anticipate incurring significant costs associated with the continued commercialization of VTAMA and that of any future product candidates, if approved, and advancing our ongoing clinical trials and discovery efforts until our revenues from product sales of VTAMA and any other approved products exceeds such expenses, which may never occur.

We may never achieve sustained 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. While we have received regulatory approval for one product candidate, VTAMA for the treatment of adults with plaque psoriasis in the U.S., and submitted an sNDA to the FDA for VTAMA for the topical treatment of AD in adults and children 2 years of age and older, we have not yet received marketing approval for any of our other product candidates anywhere in the world and we have not generated significant product revenues from the commercial sale of our biopharmaceutical products. We cannot estimate with precision the extent of our future losses. Since inception, we have incurred significant losses and negative cash flows from operations. As of March 31, 2024, we had cash, cash equivalents and restricted cash of approximately \$6.6 billion and retained earnings of approximately \$576.2 million.

We may never be able to develop or successfully commercialize new marketable drugs or achieve sustained profitability. To achieve sustained profitability, we must succeed in developing and commercializing products that generate significant revenue. Revenue from the sale of any products or 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 have or may 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. For example, even though VTAMA for the treatment of adults with plaque psoriasis has received regulatory approval in the U.S. and we have submitted an sNDA to the FDA for VTAMA for the topical treatment of AD, we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize VTAMA for other indications or in other jurisdictions. Even if we achieve profitability from product revenues 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 products and, if approved, product candidates, and continue our operations.

We may never generate meaningful product revenue from the commercial sales of our products or, if approved, product candidates or achieve or maintain profitability. It is possible that we will incur substantial operating losses for the foreseeable future. Our ability to generate meaningful product revenue and achieve sustained profitability is dependent on our ability to complete the development of our products and product candidates, obtain necessary regulatory approvals for our current and future product candidates and manufacture and successfully market our current and future products alone or in collaboration with others.

We have relatively limited experience as a commercial-stage company and the marketing and sale of VTAMA or any future products may be unsuccessful or less successful than anticipated.

In May 2022, the FDA approved VTAMA for the treatment of adults with plaque psoriasis in the U.S. While we have launched VTAMA in the U.S., we have relatively limited experience as a commercial-stage company and therefore face significant risks and uncertainties relating to the commercialization of VTAMA and any future products that receive marketing approval in the U.S. or another jurisdiction, including:

- our ability to recruit and retain effective sales, marketing and customer service personnel;
- our ability to obtain and retain access to physicians or persuade adequate numbers of physicians to prescribe VTAMA and any future products;
- the inability to manufacture and to price VTAMA and any future products at a price point sufficient to ensure an adequate and attractive level of profitability;
- the extent to which coverage and adequate reimbursement for VTAMA and any future products will be available from government health administration authorities, private health insurers and other organizations;
- the risks associated with potential co-promotion or partnership agreements, including the failure to realize the expected benefits of such arrangements;
- the costs and other risks associated with expansion of a commercial product into multiple indications, including increased sales and marketing costs; and
- other unforeseen costs, expenses and risks associated with the commercialization of biopharmaceutical products, including compliance costs.

In February 2024, we submitted an sNDA to the FDA for VTAMA for the topical treatment of AD for adults and children 2 years of age and older. To the extent that we receive FDA approval for VTAMA in that indication, or receive regulatory approval for VTAMA or any of our future products or product candidates in any other jurisdictions, we would expect to incur additional increased cash costs associated with those commercial activities.

Our relatively limited experience as a commercial-stage company means that there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry. Further, given our relatively limited experience of commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. As we continue to develop and seek regulatory approval of additional products and product candidates, as well as additional indications for VTAMA, and to pursue regulatory approvals for VTAMA and other products and product candidates outside the U.S., it could be difficult for us to obtain and devote the resources necessary to successfully pursue our commercialization efforts. If we are unable to manage the risks and uncertainties associated with the commercialization of VTAMA and any future products or product candidates that receive marketing approval, we may be unable to generate significant revenues from the sales of these products and product candidates or to achieve profitability, which will materially affect our business, prospects, financial condition and results of operations.

Our inability to successfully commercialize VTAMA or the failure of any of our product candidates in ongoing or future clinical trials or preclinical studies, in addition to having a direct adverse impact on our business and prospects, could also 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. Our business and prospects would be materially harmed by any such failures and our results of operations and financial condition would likely suffer materially as a result.

Our business is dependent to a significant extent on the successful commercialization of VTAMA and the development, regulatory approval and commercialization of our current and future products and product candidates.

We currently have one product approved by the FDA: VTAMA, which was approved for the treatment of plaque psoriasis in adults in the U.S. in May 2022. In February 2024, we submitted an sNDA to the FDA for VTAMA for the topical treatment of AD for adults and children 2 years of age and older. The success of our business, including our ability to generate any substantial revenues in the future, will depend to a significant extent on the successful commercialization of VTAMA and the successful development, regulatory approval and commercialization of our other current and future products and product candidates. The commercial success of VTAMA and the clinical and commercial success of our other current and future products and product candidates will depend on a number of factors, including the following:

- our ability to successfully implement and execute on a marketing strategy for VTAMA and to commercialize any of our current or future products in the U.S. and internationally, whether alone or in collaboration with others;
- acceptance by physicians, payers and patients of the benefits, safety and efficacy of VTAMA or any of our current or future products, including relative to alternative and competing treatments;
- timely completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our current or future products or product candidates;
- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our current or future products or product candidates by the FDA and foreign regulatory authorities;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with VTAMA or our current or future products or product candidates;
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities for our current or future products or product candidates;
- achieving, maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to VTAMA or any of our current or future products or product candidates;
- the willingness of physicians and patients to utilize or adopt VTAMA and any of our current or future products or product candidates, if approved;
- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of VTAMA or any of our current or future products or product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with Current Good Manufacturing Practice (“cGMP”);
- the availability of coverage and adequate reimbursement from private third-party payers and governmental healthcare programs for VTAMA and any of our current or future products or product candidates, such as Medicare and Medicaid;
- patient demand for VTAMA and any of our current or future products or product candidates;
- our ability to establish and enforce intellectual property rights in and to any of our current or future products or product candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- the ability to raise any additional required capital on acceptable terms, or at all.

Further, competitors who are developing products in the dermatology field or that target the same indications as us with products that have a similar mechanism of action may experience problems with their products that could indicate or result in class-wide problems or additional requirements that would potentially harm our business. Due to these risks and uncertainties, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of VTAMA or any of our current or future products or product candidates to achieve or maintain profitability.

We may not be successful in our efforts to acquire or in-license new product candidates, and newly acquired or in-licensed product candidates may not perform as expected in clinical trials or be successful in eventually achieving marketing approvals.

The success of our business depends in large part on our ability to successfully identify new product candidates, generally through acquisitions or in-licensing transactions. 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 underserved or undervalued. Once identified, we typically seek to in-license these assets from partners for low or no upfront payment, with future royalty or milestone payments to the licensor tied to the successful achievement of pre-specified development or commercialization benchmarks. From time to time, we also use joint venture structures for our Vants, where the licensor receives a minority equity ownership stake in the Vant formed around an in-licensed asset. Certain potential licensors may be unwilling or unable to pursue these types of transaction structures, which could have the effect of limiting the number of available in-licensing candidates or make us a less attractive partner for a given asset, relative to other potential acquirors.

Following the acquisition or in-licensing, our strategy often entails designing low-cost studies for a product candidate that result in a quick “go/no-go” decision on whether or how to proceed with future development for a given asset. We may decide to proceed with the development of a product candidate on the basis of that study and later determine that the more costly and time intensive trials required for regulatory approvals do not support the initial value the product candidate was thought to hold or demonstrate the product profile required for a marketing approval. Even if a product candidate does prove to be valuable or successful in receiving marketing approval, its value may be less than we anticipated at the time of the investment, including after payments of applicable royalty and milestone payments to the licensor, and we may not be able to recover our investment into the development of the product candidate.

We also face significant competition for attractive investment opportunities. A number of companies compete with us for such opportunities, some of which may possess greater financial or technical resources. If we are unable to identify a sufficient number of potential product candidates for acquisition or in-licensing, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to successfully develop or receive marketing approval for those product candidates, and our business and results of operations may suffer materially as a result. Any such failure to in-license or acquire new product candidates from third parties, or the failure of those product candidates to succeed in clinical trials and eventually receive marketing approval, would have a material adverse effect on our business, financial condition, results of operations and prospects.

We face risks associated with the allocation of capital and personnel across our businesses.

Because we have finite financial and management resources, we have to make challenging decisions regarding the allocation of capital and personnel across our businesses. We face certain risks associated with these decisions and may fail to capitalize on viable commercial product candidates or profitable market opportunities. For example, we may decide not to pursue a particular in-licensing or acquisition opportunity, or a potential target indication for a product candidate, that later proves to have greater commercial potential than our current and planned development programs and product candidates. Similarly, our management’s attention to one product or product candidate may divert their attention from another opportunity that ultimately might have proven more successful. Our spending on current and future research and development programs and other future product candidates 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 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 candidate.

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, legal and human resources expertise. Efforts to do so may not result in the actual acquisition or in-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, would have a material adverse effect on our business, financial condition, results of operations and prospects.

We face risks associated with the Vant structure.

Our products and product candidates are developed at our Vants, which operate similarly to independent biopharmaceutical companies with their own management teams and equity incentive structures. 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 Roivant and the Vants, as certain functions or processes, including sales and marketing, clinical and nonclinical personnel, business development, finance, accounting, human resources and legal functions, are replicated at Roivant and at multiple 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 adverse impacts to commercialization or development work 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 be derived from one or a small number of Vants. For example, our only approved product, VTAMA, was developed and is being commercialized by Dermavant, one of our Vants. Any adverse development at Dermavant or any other Vant, including the loss of key members of management, the termination of a key license agreement or other loss of the intellectual property underlying a product or 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 do not wholly own many of our Vants. Our Vants have equity incentive plans, which can dilute our ownership interest in the Vant as those awards vest and are exercised, and certain of our Vants have issued debt or equity securities senior to our ownership interests, which dilutes our economic interest in the Vants and can in certain cases, such as our publicly traded subsidiary Immunovant, limit our operational control of the Vant. The vesting and exercise of incentive equity awards at the Vants, as well as future capital needs at the Vants – which may be financed through senior debt or equity securities or common equity – may further dilute or subordinate our ownership and economic interests in the Vants or reduce our operational control of the Vants. In addition, recipients of Vant equity awards may have economic alignment with a Vant that incentivizes them to act in ways that prioritize the success of a Vant over the success of the Company as a whole, which could adversely impact our consolidated business, financial condition, results of operations or prospects. For more information on our ownership of our Vants, see “Business–Overview–Vant Ownership.”

We manage the Vants in part through our designees who serve on the Vant boards of directors. In their capacities as directors, those individuals may 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 as a shareholder. 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.

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

Our asset in-licensing transactions typically involve zero or low upfront payments combined with milestone and royalty payments. These arrangements generally involve a payment or payments upon the achievement of certain development or regulatory milestones, including regulatory approval, and then royalty payments upon the achievement of specified levels of sales, which can extend for up to the life of a product. Some of these payments may become due before a product is generating sufficient funds to enable us to meet our obligations. If this were to occur, we would default on our payment obligations and could face penalties, delays in commercialization or development activities, the termination of a license agreement or reputational damage. Even for a product that 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 and our ability to in-license future product candidates could be impaired.

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

Our business strategy and plans for future growth rely on a number of assumptions, including, in the case of our products and product candidates, assumptions related to adoption of a particular therapy, incidence and prevalence of an indication, use of a product or product candidate versus competitor therapies and size of the addressable patient populations. Some or all of these assumptions may be incorrect due to errors or mistaken assumptions in our analysis or the inherent uncertainties in the drug development process, among other reasons. We cannot accurately predict whether our products or product candidates will achieve significant market acceptance in line with these assumptions or whether there will be a market for our products or product candidates that reaches the anticipated size. If any of these assumptions are incorrect or overstated, our results and future prospects will be materially and adversely affected.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, including acquisitions or divestitures of companies, asset purchases or sales and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spinoffs, strategic partnerships, joint ventures, collaborations, restructurings, divestitures, business combinations and investments. For example, in December 2023, we completed a transaction to sell Telavant, which was owned by us and Pfizer, to Roche for aggregate upfront consideration of \$7.1 billion and a near-term, one-time milestone payment of \$150 million (the “Roche Transaction”). Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our or our Vants’ equity securities, including our common shares, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, and could expose us to the risk of litigation, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions, which may or may not include using all or a portion of the cash proceeds from the Roche Transaction as consideration, may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management, as well as significant costs, whether or not successfully consummated. In addition, the integration or separation of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the transaction. For any alliances or joint ventures that we enter into in the biopharmaceutical industry, we may encounter numerous difficulties in discovering, developing, manufacturing and marketing any new products or product candidates related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. Divestiture transactions such as the Roche Transaction may adversely impact the price of our common shares, to the extent investors believe the value of the consideration received in the transaction is not equivalent to the value of the asset or program divested. Accordingly, there can be no assurance that transactions of the nature described above will be undertaken or successfully completed, and that any transaction we do complete will not have a material adverse effect on our business, results of operations, financial condition and prospects.

We face risks associated with the use of our cash, cash equivalents and restricted cash, including any return of capital to shareholders.

As of March 31, 2024, we had cash, cash equivalents and restricted cash of approximately \$6.6 billion, which includes the cash proceeds from the Roche Transaction. Our management team has broad discretion in respect of use of our cash, cash equivalents and restricted cash, including the proceeds from the Roche Transaction. We may use all or a portion of such proceeds for one or more strategic transactions, including acquisitions of companies, asset purchases or sales or in-licensing of intellectual property, products or product candidates or technologies, as described above. We may not be able to find a suitable strategic transaction that we deem sufficiently attractive to pursue, and may not be able to complete a strategic transaction in the future. Our ability to complete a strategic transaction may be negatively impacted by general market conditions, volatility in the capital markets and the other risks described herein.

We may also decide to return capital to shareholders through one or a combination of public or private share repurchases, or the issuance of cash dividends on our common shares. As previously disclosed, our board of directors has authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to \$1.5 billion (excluding fees and expenses) (the “2024 Repurchase Program”). A portion of the 2024 Repurchase Program, approximately \$648.4 million, was used to repurchase all of the common shares held by Sumitomo Pharma Co., Ltd. in April 2024.

The timing and total amount of any additional common shares repurchased under the 2024 Repurchase Program or any future repurchase authorization from our board of directors will depend on several factors, including the market price of our common shares, general business, macroeconomic and market conditions and other investment opportunities, as well as the discretion of our board of directors, or its delegates, that any such activity would be in the best interests of our shareholders and in compliance with all applicable laws and our contractual obligations. In the event that we decide to pursue further repurchases of common shares, we may be limited in our ability to repurchase our common shares by various governmental laws, rules and regulations which prevent us from purchasing our common shares during periods when we are in possession of material non-public information. We may also use our discretion to repurchase common shares from certain shareholders without offering the opportunity to all shareholders to have their common shares repurchased at that time and price. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur.

The amount of cash available to return to shareholders, if any, can vary significantly from period to period for a number of reasons, including, 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. The returns of capital to shareholders may change in form, amount, value and frequency from time to time, and we cannot guarantee that any such future returns of capital will take place. The trading price of our common shares may decline, possibly materially, if we are unable to meet investor expectations with respect to the timing and total amount of future capital returns to shareholders. There is no guarantee that our significant balance of cash, cash equivalents and restricted cash, including the proceeds from the Roche Transaction, will be used to increase our operating results, return capital to shareholders or enhance the value of our common shares.

We are exposed to risks related to our significant holdings of cash, cash equivalents and restricted cash.

Our significant holdings of cash, cash equivalents and restricted cash can be negatively affected by changes in liquidity, financial results, market and economic conditions, political risk, currency risk, credit risk, sovereign risk, interest rate fluctuations or other factors. As a result, the value and liquidity of our cash, cash equivalents and restricted cash may fluctuate substantially. Additionally, we may from time to time have balances in bank accounts that are in excess of insured deposit limits, and could be subject to risks of bank failures. Therefore, although we have not realized any significant losses on our cash, cash equivalents and restricted cash, future fluctuations in their value could result in significant losses and could have a material adverse impact on our results of operations and financial condition.

We may require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to successfully market our products, acquire or in-license new products or product candidates, complete the development and commercialization of our products and product candidates and continue to pursue our drug discovery efforts.

Acquiring or in-licensing, discovering, developing, commercializing and marketing biopharmaceutical products and product candidates is expensive and time consuming, and, in the future, we may require additional capital to pursue these activities. We are also responsible for payments to third parties under our license and acquisition agreements, including milestone and royalty payments. Because of the inherent uncertainties in these activities – including the outcome of preclinical and clinical trials and the regulatory approval process – we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our current and future products and product candidates.

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

- the time and costs necessary to complete our ongoing, planned and future clinical trials for our current and future products and product candidates;
- the time and costs necessary to pursue regulatory approvals for our current and future product candidates;
- the costs associated with future acquisitions or in-licensing transactions;
- the approval, progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner for our ongoing and planned clinical trials and potential future clinical trials for our current and future product candidates;
- the costs associated with our ongoing, planned and future preclinical studies and other drug discovery activities;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations (“CMOs”);
- the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our current and future products and product candidates;
- our ability to successfully commercialize VTAMA, including:
 - o the manufacturing, selling and marketing costs associated with VTAMA, including the cost and timing of expanding sales and marketing capabilities or entering into strategic collaborations with third parties; and
 - o the amount and timing of sales and other revenues from VTAMA, including the sales price and the availability of adequate third-party reimbursement;

- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, including current and future patent infringement actions brought against third parties, for our current and future product candidates;
- the cost of pursuing and defending potential intellectual property disputes, including patent infringement actions with third parties, relating to our current or future products or product candidates; and
- our ability to hire, attract and retain qualified personnel.

In the event that we require additional financing, we cannot be certain that additional capital will be available to us or the Vants on acceptable terms, or at all. If we or the Vants 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 our in-licensing and acquisition, discovery, development, commercialization and marketing activities. 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 and future product development programs and discovery efforts. Moreover, risks associated with broader market conditions, including high levels of inflation, heightened interest rates and increasing market and banking sector instability and volatility, all of which have been observed in recent periods, may further adversely impact our ability to obtain financing on acceptable terms or at all.

In the future, we may require significant additional capital to continue our operations, pursue business opportunities or strategic transactions, or respond to challenges, competition or unforeseen circumstances. Until such time, if ever, that we can generate substantial revenues, we may finance future cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations at Roivant and the Vants. To the extent that we raise additional capital by issuing equity securities at Roivant or the Vants, our existing shareholders' ownership, or our ownership in the Vants, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of our shareholders. 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 products and 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 adequate funds are not available to us, we may be required to forego potential in-licensing or acquisition opportunities, delay, limit or terminate one or more development or discovery programs, scale back marketing efforts for our current and future products or be unable to expand operations or otherwise capitalize on business opportunities, which could materially affect our business, prospects, financial condition and results of operations.

We may not be able to complete certain strategic transactions if a proposed transaction may be subject to review or approval by regulatory authorities pursuant to certain U.S. laws or regulations.

Certain potential acquisitions, divestitures or other business combinations that we may pursue could be subject to review or approval by regulatory authorities pursuant to certain U.S. laws or regulations. In the U.S., certain mergers that potentially could affect competition may require certain filings and review by the Department of Justice and the Federal Trade Commission. In recent years, there has been enhanced regulatory scrutiny over such transactions. In the event that we were to make an investment, acquisition or disposition that was determined to be subject to regulatory review, and such regulatory approval or clearance is not obtained, or the review process is extended beyond the period of time that would permit such strategic transactions to be consummated, we may not be able to consummate such strategic transactions or counterparties may be deterred from pursuing potential strategic transactions with us. This may impair our ability to raise capital when needed and to pursue accretive transactions, which is an important part of our business model, and have an adverse effect on our business, financial condition and prospects.

Our drug discovery efforts may not be successful in identifying new product candidates.

Our drug discovery efforts are centered on our discovery Vants, including Psivant, Covant and VantAI, which employ a variety of approaches to the drug discovery process, including quantitative proteomics, induced proximity and covalency. As a company, we have relatively limited experience in drug discovery generally and with certain of the computational tools that are employed in those efforts. Our future success depends, in part, on our ability to successfully use these approaches and technologies to identify promising new product candidates and eventually advance those product candidates through preclinical studies and clinical trials. We have not yet succeeded and may not succeed in advancing any product candidates developed through these discovery efforts into clinical trials, demonstrating the efficacy and safety of such product candidates or obtaining regulatory approval thereafter. As a result, it is difficult to predict the time and cost of product candidate development from our discovery Vants and we cannot predict whether the application of these approaches will result in the development and regulatory approval of any products. In addition, many of the active drug discovery efforts at our discovery Vants are being conducted pursuant to collaboration agreements with third parties, in which the third parties are either owed milestone and royalty payments tied to the successful development and commercialization of successfully identified drug candidates, or have been granted exclusive or shared development and commercialization rights with respect to successfully identified drug candidates in exchange for upfront payments, shared expenses, and certain milestone and royalty payments owed to the discovery Vants. Any problems that we or our third party partners 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. Even if successful, as a result of our collaboration agreements, our rights to commercialize any successfully discovered product candidates may be limited.

Risks Related to the Development of Our Products and Product Candidates

Clinical trials and preclinical 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 preclinical studies on the expected timelines, if at all.

Our biopharmaceutical product candidates that are in clinical development or preclinical studies 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 preclinical testing before an Investigational New Drug application (“IND”) or an application for authorization to conduct a clinical trial in the EU or UK may be submitted, a Clinical Trial Application (“CTA”). We cannot provide any assurance that we will submit an IND, NDA, CTA or other similar application for regulatory approval for our product candidates within projected timeframes or whether any such application will be accepted for review or ultimately approved by the relevant regulatory authorities.

Clinical trials and preclinical 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, BLA or similar application. The FDA, the European Medicines Agency (“EMA”), the European Commission, the Medicines and Healthcare product Regulatory Agency (“MHRA”) 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 clinical trial application or 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 the EU, data derived from clinical trials that were conducted outside the EU cannot be used to support a CTA unless the clinical trial was registered on a relevant database. In each case, this could delay the clinical development and authorization timeline for a given product candidate.

Failures can occur at any stage of development, including clinical trials or preclinical studies, and we could encounter problems that cause us to abandon or repeat clinical trials or preclinical studies. In addition, results from clinical trials or preclinical studies may require further evaluation, delaying the next stage of development or submission of an IND or an NDA or similar application in the U.S. or another jurisdiction. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having successfully progressed through preclinical and earlier stage clinical trials. Such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in earlier studies or trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials with a product candidate due to lack of efficacy or adverse safety findings, despite having promising results in earlier trials or studies. Likewise, the results of early clinical trials or preclinical studies of our product candidates may not be predictive of the results of current or future development programs. There can also be no assurance that the results of studies conducted by collaborators or other third parties with similar product candidates in similar indications will be viewed favorably or indicative of our own future trial results.

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

- failure to obtain regulatory authorization to commence a clinical 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 experiencing 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 candidates 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.

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, or the principal investigator, are failing to conduct a trial in accordance with the protocol, 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. In addition, disruptions caused by any ongoing effects of the COVID-19 pandemic or future pandemics may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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 preclinical 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 authorities 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 authorities, 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 products or product candidates that are in clinical development, prior to our acquisition of the rights to those products or product candidates we had no involvement with or control over the preclinical or clinical development of those products or product candidates. We are therefore dependent on our licensing and other transaction partners having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having used appropriately regulated and compliant equipment and devices during the preclinical or clinical development, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to those products or 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 products or product candidates. Problems associated with the pre-acquisition development of our products or product candidates could result in increased costs and delays in the commercialization of our products or development of our product candidates, which could harm our ability to generate any future revenue from sales of products or, if approved, product candidates.

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 products or 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 products or 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 products and product candidates.

Patient enrollment and retention in clinical trials depends on many factors, including EC approval of patient participation as proposed, 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, including those related to any ongoing effects of COVID-19 pandemic or future pandemics, 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 and our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our products and product candidates, including IMVT-1402 and batoclimab, which target certain 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 products or 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. 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 products and product candidates, or could render further development impracticable. 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. Any such delays in our current or future clinical trials could have a material adverse impact on our operations and financial condition and results.

The results of our preclinical studies and clinical trials may not support our proposed claims for our products or 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 preclinical studies 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 preclinical studies and earlier clinical trials. For example, we cannot assure you that the reductions in IgG antibodies and favorable analyte profile observed in our Phase 1 trial of IMVT-1402 will be observed in future clinical trials, including pivotal trials necessary for regulatory approvals. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. 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 were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unobserved adverse events.

The results of preclinical studies and early clinical trials of our products and product candidates may not be predictive of the results of later-stage clinical trials. Products and product candidates in later stage clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints may cause us to abandon development of the product candidate in question. Any delay in, or termination of, our clinical trials will prevent or 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 products or, if approved, our product candidates, 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 products and product candidates. The FDA and other regulatory authorities, including the EMA and the MHRA, have 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, and in some countries, in line with the applicable requirements set out in legislation and guidance, 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. For example, we previously disclosed 24-week data from our NEPTUNE trial of brepocitinib in non-anterior non-infectious uveitis, results from the initial cohort of patients in our Phase 2 trial of batoclimab in Graves' disease and initial human data from our Phase 1 trial of IMVT-1402. These 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 reported. 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, other parties, 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 a particular product or product candidate and our business in general. In addition, the information we choose or are required 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. 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 our products and 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 our products and product candidates proceed through the development process, 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 products or 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, or another regulatory authority's notification or approval, as applicable, since similar requirements apply in other jurisdictions. This could delay the completion, or result in the abandonment, of clinical trials, require the conduct of bridging clinical trials, the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our products and 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 nonclinical 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 contract, protocol, legal, regulatory and scientific standards and that clinical trial sites meet applicable protocol and regulatory requirements. Our reliance on CROs does not relieve us of our regulatory or specified contractual responsibilities.

We and our CROs are required to comply with 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 products and product candidates that are in preclinical 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. Our expected reliance on the CROs does not relieve us of our regulatory or contractual 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 non-U.S. regulatory authorities may reject our marketing authorization applications and require us to perform additional clinical trials to generate additional data 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 are independent, third-party organizations and we do not control whether they devote sufficient time, attention and resources to our 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 or product candidate that we develop. As a result, our financial results and the commercial prospects for any product or 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 rely on third parties to produce clinical and commercial supplies of our products and product candidates.

We do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Accordingly, we rely on third parties to produce commercial and clinical supplies of our products and product candidates. For example, Dermavant, ThermoFisher and GSK have entered into agreements pursuant to which ThermoFisher and GSK are providing commercial drug product and drug substance for VTAMA as well as drug product and drug substance for Dermavant's completed pivotal atopic dermatitis Phase 3 ADORING 1 and ADORING 2 trials of VTAMA as well as its ongoing open label long-term extension study of VTAMA in atopic dermatitis. If these counterparties do not fulfill their obligations under these agreements, Dermavant's ability to sell VTAMA commercially and conduct its ongoing and future clinical trials with VTAMA may be adversely impacted.

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 products or product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our products for commercialization and products or product candidates for our preclinical studies, clinical trials and research and development activities. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, or of equipment and devices as necessary, for either commercialization or an ongoing clinical trial, due to the need to replace a third-party manufacturer or otherwise, could considerably delay marketing efforts for the product in question or the completion of clinical trials, product testing and potential regulatory approval of the product candidate in question. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our products or product candidates, the commercial launch of our products or 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 products or product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our products or 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 involve committing substantial financial resources to current or future products or product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals were recently enacted or are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the U.S. 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 products and 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 cGMP requirements for the manufacture of products and 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 products or 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 products or 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 market our products and 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 our products and 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 products or 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 products or 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 products and 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 products and product candidates for clinical trials or commercial sale, including our existing CMOs for all of our products and 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 U.S. These regulations govern manufacturing processes and procedures, including record-keeping, 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 products and 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 or 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 products or product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our products and 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 products and product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products and product candidates 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 and product candidates 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 products and 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 or 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 products and 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.

Certain of our products and 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 CMOs use to produce our products and product candidates are complex, novel and, in the case of our product candidates, 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 biologic 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, the UK or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA, the MHRA and other 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, the MHRA 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 processes 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 biopharmaceutical companies and academic research institutions, which could limit access to additional attractive development programs. Problems in any of our manufacturing processes could restrict our ability to meet potential future market demand for our products or to conduct clinical trials with our product candidates.

Risks Related to Regulatory Approval and Commercialization of Our Products and 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 products or 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 nonclinical 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. While we have obtained regulatory approval in the U.S. for one of our product candidates, VTAMA, for the treatment plaque psoriasis in adults, and have submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD for adults and children 2 years of age and older, it is possible that VTAMA will not receive this regulatory approval or obtain any other regulatory approvals in the U.S. for other indications or in other jurisdictions, and that other current and future product candidates will not be successful in obtaining regulatory approval in the U.S. and other jurisdictions. In addition, we cannot be certain that any products or product candidates that receive regulatory approval will be successfully commercialized.

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 preclinical 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, preclinical 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, preclinical 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, including in situations where the authorities deem that the data was not generated in compliance with GCP, ethical standards or applicable data protection laws;

- if an NDA, BLA or a similar application is referred for review 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 authorities, as the case may be, require, as a condition of approval, additional nonclinical, preclinical studies or clinical trials, limitations on approved labelling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy (“REMS”) drug safety program 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 candidates;
- 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 nonclinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from nonclinical 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 nonclinical studies, preclinical 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 relatively limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support additional marketing approvals.

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 when regulatory approval is secured for a product or 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 products and 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 or associated with our products and product candidates have caused us and could, in the future, 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 their participation in our clinical trials 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, as previously disclosed, in early 2021, our subsidiary Immunovant voluntarily paused dosing in early phase clinical studies for batoclimab to evaluate treatment-induced elevations in total cholesterol and LDL levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory agencies, Immunovant is continuing its clinical development of batoclimab. While Immunovant does not expect that increases in LDL over a short-term treatment duration would 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. These occurrences have harmed, and any reoccurrence may continue to harm our business, financial condition and prospects.

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

- regulatory authorities may withdraw, revoke, suspend, vary, or limit their approval of the product or require a REMS (or equivalent outside the U.S.) to impose restrictions on its distribution or other risk management measures;
- regulatory authorities may request or require that we recall a product;
- additional restrictions being imposed on the distribution, marketing or manufacturing processes of the products or any components thereof, including a “black box” warning or contraindication on product labels or communications containing warnings or other safety information about the product;
- regulatory authorities may require the addition of labelling statements, such as warnings or contraindications, require other labelling 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 distributed, conduct additional clinical trials, change the labelling of a product or conduct additional post-marketing studies or surveillance;
- we may be required to repeat preclinical 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 may be sued and held liable for harm caused to patients, or may be subject to fines, restitution or disgorgement of profits or revenues;
- physicians may stop prescribing a product;
- reimbursement may not be available for a product;
- we may elect to discontinue the sale of our products;
- our products 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 products or product candidates, substantially increase the costs of commercializing our products or product candidates in the future 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 gaining approval for a product candidate in one country or jurisdiction does not guarantee that we will be able to 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 authorities, that such product candidate is safe and effective and, as applicable, pure and potent for its intended use. Results from nonclinical 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 of a product candidate by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the U.S. In addition, clinical trials conducted in one country, and the data generated therefrom, 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 have one product, VTAMA, which has been approved by the FDA for the treatment of plaque psoriasis in adults in the U.S., and have submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD, but do not have any other products approved for sale in the U.S. or any other jurisdiction, including in international markets, and we do not have significant experience in obtaining regulatory approval in other markets. 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.

FDA approval for a product candidate in the United States does not guarantee that we will be able to or that we will make efforts to 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.

We have one product, VTAMA, approved by the FDA for the treatment of plaque psoriasis in adults in the U.S. We have also submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD. In order to market VTAMA or any of our other products or product candidates outside of the U.S., 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 U.S., including additional preclinical 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 U.S., 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 U.S. 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 process outside of the U.S. may include all of the risks associated with obtaining FDA approval. Other than VTAMA, we do not have any products or product candidates approved for sale in any jurisdiction, including international markets, and we do not have significant 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.

Following regulatory approvals for our products and product candidates, we will continue to face extensive ongoing quality and regulatory obligations and continued regulatory review, which may result in significant additional expense, and our products may face future development and quality or regulatory compliance difficulties.

We have one product, VTAMA, approved by the FDA for the treatment of plaque psoriasis in adults in the U.S. We have also submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD. Any product or 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, labelling, packaging, distribution, adverse event reporting, storage, recordkeeping, traceability, conduct of potential post-marketing studies and post-marketing 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 cGMP or equivalent requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, prior notification/review and/or approval of advertising and promotional materials by the competent authorities, record-keeping and GCP requirements for any clinical trials that we conduct post-approval. Even when marketing approval of a product or 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. When a product or 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 labelling or accompanying documentation, 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, result in regulatory enforcement, or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulate 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 labelling 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 products or 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 and the UK we will be prohibited from promoting prescription-only medicinal products to individuals who are not healthcare professionals. Violations of the FDCA in the U.S. and other comparable laws and 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 U.S. 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 products or 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 of such products or product candidates;
- restrictions on the labelling or marketing of such products or 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 U.S.);
- Warning or Untitled Letters or similar communications from other relevant regulatory authorities;
- withdrawal of the product or product candidates from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products or product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products or product candidates;

- seizure of our products or product candidates; 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.

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

Quality management plays an essential role in the 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 products and product candidates. We seek 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, injunctions 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 products or product candidates, which may result in difficulty in successfully launching products and the loss of potential future sales, which could have an adverse effect on our business, financial condition, and results of operations.

Breakthrough Therapy Designation, Fast Track 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 or Orphan Drug Designation for certain of our product candidates. For example, in July 2021, Immunovant was granted orphan drug designation in the U.S. by the FDA for batoclimab for the treatment of MG and, in August 2022, it received orphan drug designation from the European Commission for batoclimab for the treatment of MG. Immunovant plans to seek orphan drug designation from the FDA for IMVT-1402 and/or batoclimab where there is a medically plausible basis for IMVT-1402 and batoclimab’s use. Immunovant may also seek orphan drug designation for IMVT-1402 and batoclimab for the treatment of other indications in the E.U. We may also do so for other of our products and product candidates in the future where there is a basis for doing so.

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 on 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.

Recently, there has been heightened scrutiny of the accelerated approval pathway, with some stakeholders advocating for reform. The HHS Office of Inspector General has initiated, and partly completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Consolidated Appropriations Act, 2023, revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things, requires the FDA to specify the conditions for required post-marketing trials, permits the FDA to require such trials to be underway prior to, or within a specific period after, approval, requires sponsors to provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed, makes the failure to conduct required post-marketing trials with due diligence and the failure to submit the required reports prohibited acts, and details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis. We understand that FDA approval letters to products granted accelerated approval subsequent to passage of this legislation are including language that informs the sponsor that they are required to submit status reports of the progress of each requirement no later than 180 days post-approval and every 180 days thereafter. Further, we understand that a company received a Complete Response Letter for a product seeking accelerated approval in two indications because enrollment had not yet begun for confirmatory portions of ongoing clinical trials. At this time, it is not clear what impact, if any, these developments may have on our business, financial condition results of operations or prospects.

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 it believes 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 U.S. and the European Economic Area (the "EEA"), may designate drugs and biologics for relatively small patient populations as orphan drugs. In the U.S., 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 U.S. 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 U.S. 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 U.S., 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 of marketing exclusivity is seven years in the U.S. A similar market 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 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 Drug 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 certain benefits, such as scientific assistance (protocol assistance), 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, EMA 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 preclinical 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 or biosimilar 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, during the first eight years of the ten years market exclusivity, a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic or biosimilar 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.

In April 2023, as part of the EU Pharmaceutical Strategy, the European Commission published a proposal for a comprehensive revision of the EU pharmaceutical legislation (which will not apply in the UK). If adopted by the European Parliament and the Council, the new legislation is likely to significantly change the regulatory regime applicable to both the “normal” data and market exclusivity and the orphan exclusivities and reduce/modulate the exclusivities and rewards that could be granted to medicinal products. In addition, the proposal envisages changes to the concept of unmet medical need and considers introducing novel rewards for orphan medicinal products addressing a high unmet medical need. The adoption of the new legislation is not expected before 2025 and it will start to apply 18 months after the entry in force.

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 European Commission 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. Moreover, our orphan exclusivity may be reduced if we are unable to comply with any new obligation that may be imposed by the upcoming reform of the EU pharmaceutical legislation, as discussed above.

Moreover, a September 2021 Eleventh Circuit decision in *Catalyst Pharmaceuticals, Inc. vs. Becerra* regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug’s orphan designation could significantly broaden the scope of orphan drug exclusivity for such products. In January 2023, the FDA, however, issued a Federal Register notice clarifying its approach to orphan drug exclusivity following the *Catalyst* decision. Consistent with the court’s decision, the FDA set aside its approval of the drug at issue in the case, but announced that, while complying with the court’s order in *Catalyst*, the FDA intended to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order. Legislation has also been introduced that may reverse the *Catalyst* decision.

Receipt of marketing approval for our products and product candidates does not guarantee that they will achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

The commercial success of our products and product candidates will depend upon their degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Receipt of marketing approval for our products and product candidates does not guarantee that they will gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance for any product or product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such products and 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 or product candidate is approved by FDA or comparable non-U.S. regulatory agencies;

- product labelling 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 labelling;
- 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 adverse events.

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 "Affordable Care Act" or "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 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 preclinical 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. 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 the 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. 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 variable, and will depend on a number of marketplace and regulatory factors. 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.

Our commercialization efforts are dependent on our sales, marketing and distribution capabilities, including agreements with third parties to sell, market and distribute our products and product candidates.

In order to effectively market our products and product candidates, we must successfully employ our sales, distribution, marketing and related capabilities or make arrangements with third parties to perform these services. Our subsidiary Dermavant has established a commercial sales organization for the sales, marketing and distribution of VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U.S. Other Vants with product candidates in late-stage clinical development, including Immunovant, do not currently have a sales, marketing and distribution infrastructure, and would expect to build a sales, marketing and distribution function, or make arrangements with third parties to perform these services.

There are risks involved with both establishing and maintaining internal 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 or, if approved, 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. At Dermavant, the costs of maintaining this sales, marketing and distribution infrastructure may exceed the net revenues we are able to generate from the sale of VTAMA.

Factors that may inhibit our efforts to commercialize a product or, if approved, product candidate 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 a product or, if approved, product candidate, we may be forced to delay commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we may 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 a product or, if approved, 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 products or 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. 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 products or, if approved, product candidates.

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 products and, if approved, product candidates. 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 \$13,508 to \$27,018 for each false claim or statement for penalties assessed after January 30, 2023, 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 (collectively, “covered entities”), and such covered entities’ “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 the covered entity;
- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level, which impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personally identifiable data, including personal 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, including prior notification, review and/or approval of agreements with healthcare professionals, 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 and regulatory measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The U.S. and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities for our products and affect our ability to profitably sell our products, and prevent or delay marketing approval of our current and any future product candidates. 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 labelling; (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 U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs for pharmaceuticals. For example, as discussed in detail above, the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In particular, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Most notably and as described in detail above, the IRA brought about sweeping changes to the payment for drugs under the Medicare program. There are several ongoing legal challenges to the IRA's drug price negotiation program, and we cannot predict the outcome of these cases or the impact they could have on implementation of the law. Over time, the IRA could increase our government discount and rebate liabilities, reduce the revenues we are able to collect from sales of our products as well as present challenges for payor negotiations and formulary access. However, the degree of impact that the IRA will ultimately have upon our business remains unclear at this time.

Moreover, individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing, such as in Colorado and Florida, as discussed in detail above. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing.

Additionally, U.S. regulators continue to pursue policies designed to lower drug costs for federal programs and patients. In May 2019, 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. This rulemaking also created 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. However, Congress has adopted various delays on the implementation or enforcement of the rule, including a postponement until January 2032 under the IRA. On December 31, 2020, CMS enacted a final rule that, among other things, expanded the scope of drug products that may be considered “line extensions” subject to inflationary rebates under the Medicaid Drug Rebate Program. On May 23, 2023, CMS issued a Medicaid Drug Rebate Program proposed rule, which if finalized, would, among other things, require drug manufacturers to aggregate certain price concessions when calculating Best Price, establish a price verification survey, and amend the definitions of a “covered outpatient drug” and a “manufacturer.” These changes, if finalized, could deepen rebates owed on Medicaid utilization, expand the scope of products subject to Medicaid rebates, and subject manufacturer drug pricing practices to further scrutiny.

Moreover, upcoming legislative and policy changes in the EU and the UK, some of which may materialize in the near term, 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 through product revenue, or commercialize our products and, if approved, our product candidates. Such reforms could have an adverse effect on anticipated revenue from our products and, if approved, product candidates and may affect our overall financial condition and ability to develop future product candidates and obtain marketing approval for those 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 products and, if approved, product candidates;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve sustained 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 our products and, if approved, product candidates. 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 sustained profitability or successfully commercialize our products and, if approved, product candidates.

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

Market acceptance and sales of our products and, if approved, product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and product candidates and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. The pricing and reimbursement of our products and, if approved, product candidates, 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 products and, if approved, product candidates, will be adversely affected. The manner and level at which reimbursement is provided for services related to our products and product candidates (e.g., for administration of our products 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 products and, if approved, product candidates. There is no assurance that our products or, if approved, product candidates, would achieve adequate coverage and reimbursement levels.

In the U.S., no uniform policy of coverage and reimbursement 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 or, if approved, product candidate will be made on a plan-by-plan basis. For example, while we have previously disclosed successes in achieving payor coverage for VTAMA, 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, and payors may periodically review and change their coverage and reimbursement rates for products. Discussions with payors, including PBMs, related to VTAMA are ongoing and coverage for VTAMA may change over time. 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 or, if approved, product candidates, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product or product candidate. 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 products or, if approved, product candidates, to the extent that patients who are prescribed our products or, if approved, product candidates, 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, products. 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 products. 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 or, if approved, product candidate. 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 or, if approved, product candidate that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the U.S. and in some other jurisdictions that could affect our ability to profitably sell any product or, if approved, product candidate. These legislative and regulatory changes may negatively impact the reimbursement for any product or, if approved, product candidate. There can be no assurance that our products or, if approved, product candidates, 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 U.S. and in other countries where our products and, if approved, product candidates, are sold will not harm our ability to profitably sell our products and, if approved, product candidates.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products or, if approved, product candidates. In addition to continuing pressure on prices and cost containment measures, legislative developments in the EU or the EU Member States may harm our ability to profitably sell our products and, if approved, product candidates. 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, and a similar approach is taken in the UK where a key consideration is the affordability of drugs for treatment of patients under the National Health Service. In the UK there is also a budget cap on branded health service medicines, and a new voluntary pricing scheme has been introduced that increases the level of rebate payment that a company is required to make to the National Health Service to take account of any spend on branded products that is above the agreed cap, and also imposes different payment rates for newer or older medicines. A consultation on the parallel statutory scheme, which applies to companies that are not members of the voluntary scheme, is ongoing, but is also likely to lead to higher rebates than previously. In markets outside of the U.S., EU and UK, 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 products and, if approved, product candidates.

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 U.S. for our products and, if approved, product candidates, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the U.S., 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. The court dismissed the case in February 2023. 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. Several states have enacted laws intended to support importation processes and have submitted importation program proposals to FDA. On January 5, 2024, FDA authorized Florida’s importation program for the importation of certain prescription drugs from Canada into Florida; however, the state must file Pre-Import Requests for specific drug products that FDA must grant before any importation may take place. In response, Health Canada issued a statement on January 8, 2024 making clear that it is ready to take immediate action to help safeguard the Canadian drug supply if necessary. If implemented in Florida or elsewhere, importation of drugs from Canada may materially and adversely affect the price we receive for our products and, if approved, 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 other 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 our products and, if approved, product candidates 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, including our Principal Executive Officer, Matthew Gline, as well as other senior executives at Roivant and 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 preclinical 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 related 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 our key personnel or that of our 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 a 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 U.K. and Switzerland. 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 highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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, 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 our products and product candidates will be harmed, which could negatively impact our financial condition, results of operations and cash flows.

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 products and 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 products or, if approved, product candidates, 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 U.S. 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 and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by global or regional economic, political and health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), international hostilities (including the current military conflict between Russia and Ukraine and the conflict in the Middle East), trade disputes between nations and the current and future conditions in the global financial markets. For example, if sustained high rates of inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease (for example, COVID-19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our commercial sales. A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or 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 certain regulatory approvals 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 our products and, if approved, product candidates and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Now and in the future we may face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our products and product candidates. 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 and product candidates for the treatment of the indications that we are also pursuing. Examples of such competing products include, but are not limited to:

- ZORYVE (roflumilast), a topical PDE4 inhibitor, a potential competitor to VTAMA;
- OPZELURA (ruxolitinib), a topical Janus kinase inhibitor, a potential competitor to VTAMA;
- VYVGART (efgartigimod alfa-fc) and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), neonatal Fc receptor blockers, potential competitors to IMVT-1402 and batoclimab;

- Nipocalimab and RYSTIGGO (rozanolixizumab-noli), anti-FcRn antibodies, potential competitors to IMVT-1402 and batoclimab;
- TEPEZZA (teprotumumab-trbw), an insulin-like growth factor-1 receptor inhibitor, a potential competitor to batoclimab; and
- Dazukibart, an interferon beta (IFN-beta) inhibitor, a potential competitor to brepocitinib.

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, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

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 our products and product candidates. 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 products and 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 products or product candidates uneconomical or obsolete and we may not be successful in marketing our products or, if approved, 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 or product candidates 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 our products and, if approved, any product candidates we may develop.

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 Lokavant, a clinical trial technology company, and VantAI, which uses machine learning to build computational models to generate new molecular entities for targets of interest, face competition from well-established providers of similar 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.

In addition, we are facing increasing competition from other companies that are utilizing artificial intelligence ("AI") and other computational approaches for drug discovery. Some of these competitors are involved in drug discovery themselves and/or with partners, and others develop software or other tools utilizing AI which can be used, directly or indirectly, in drug discovery. To the extent these other AI approaches to drug discovery prove to be more successful than our approaches, we may not be successful in identifying potential targets or attracting collaborators to work with us.

We and our subsidiaries are subject to litigation and investigation risks which could adversely affect our 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 our 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 preclinical and clinical data, and the resulting disclosure (or lack thereof) may give rise to securities litigation.

We maintain insurance policies for certain litigation and various business risks, but such policies may not be adequate to compensate us for any or all 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, if available, 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 as they arise from time to time, and they could have a material adverse effect on our and our subsidiaries' business, results of operations, and financial condition, could impact our 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.

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

In certain of our Vants, we may hold less than a majority ownership interest or otherwise be 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 protections.

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 or otherwise be subject to 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 traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-state and nation-state-supported actors, sovereign governments and cyber terrorists, have generally increased over time, including for geopolitical reasons and in conjunction with military conflicts and defense activities, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our products and product candidates. Currently and in the coming years, there may be an increased risk of cybersecurity attacks due to the ongoing Russia-Ukraine conflict, including cybersecurity attacks perpetrated by Russia or others at its direction in response to economic sanctions and other actions taken against Russia as a result of the invasion. Any increase in such attacks on us or our third-party vendors or other systems could adversely affect our network systems or other operations.

We generally require our third-party providers to implement effective security measures and to identify and correct for any information technology security 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 incidents 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 a significant cybersecurity compromise were to occur, it could result in a material disruption of our commercialization efforts, drug development programs, and other 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 in an unauthorized disclosure of personal, confidential or proprietary information, we could incur liability and reputational damage and the commercialization efforts for our products and 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, data protection and information security laws, regulations, policies and contractual obligations related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adverse effects to our business.

Certain of our subsidiaries and affiliates collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials in the U.S. and abroad necessary to operate their businesses and for legal, marketing and other business-related purposes.

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 requirements relating to the privacy, security, transmission and disposal of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. Any failure by us, or our subsidiaries or affiliates, to comply with applicable privacy and data security 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, data protection 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 and their service providers 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 the HIPAA privacy or security regulations, we do business with various entities (including clinical trial investigators) that are subject those regulations, and we have to expend resources to understand their obligations, adjust contractual terms in light of those obligations, or otherwise modify our business practices. Congress is actively considering adopting legislation to regulate the collection, use, and disclosure of personal health information more broadly than the HIPAA privacy and security regulations. Such legislation might require us to make substantial expenditures and would likely create additional liability risks.

The Federal Trade Commission ("FTC") Act, while not focused on data privacy or security, has proven to be a significant federal enforcement tool with respect to protection of personal information, and recently, personal health information in particular. The FTC has used its authority under Section 5 of the FTC Act, which prohibits unfair and deceptive practices affecting consumers, to bring numerous cases against companies for failing to protect the privacy or security of personal information in a manner that is reasonable and fully consistent with stated privacy policies, notices, or other representations. Particularly because the FTC has taken these actions based on theories that are not codified in regulations, the optimal means to mitigate the risk of such an action are uncertain.

In addition, an increasing number of U.S. 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 complicates compliance efforts. For example, the California Confidentiality of Medical Information Act (the “CMIA”), a statute that expressly applies to pharmaceutical companies (as well as companies that provide certain 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, with limited exceptions, 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 and requires pharmaceutical companies to maintain reasonable security measures to protect such 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. Washington State’s My Health My Data Act, and a similar Nevada law, both of which became effective on March 31, 2024, generally require consent for the collection and use of personal health information, and a separate consent for sharing any such information, and create additional risk for our collection of health information. Violations of the Washington State law can result in civil penalties of up to \$7,500 per violation, up to \$25,000 in treble damages at the sole discretion of the court, and injunctive relief. Consumers also may bring their own actions to recover (i) actual damages, (ii) treble damages; and (iii) attorney’s fees. Violations of the Nevada law can result in up to \$10,000 civil penalties per violation and injunctive relief.

In addition, approximately 15 states have enacted broadly applicable consumer privacy laws, which apply not only to personal health information but also many other forms of information. These laws, including the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, the “CCPA”), typically require us to provide notice to state residents regarding our collection, use, and sharing of their personal information, and give state residents the right to opt-out of the sale or sharing for targeted advertising of their personal information, as well as the right to limit our use and disclosure of their “sensitive” (including health) personal information. Some of these laws require that we obtain signed consent in order to collect, use or share any sensitive personal information. Most of these laws are enforceable only by state authorities, but the CCPA provides a private right of action for data security breaches that result in the compromise of highly sensitive personal information, which may increase the likelihood of, and risks associated with, data breach litigation. Both the California Attorney General and the California Privacy Protection Agency, have authority to implement and enforce the CCPA.

New legislation anticipated to be enacted in various other states will continue to shape the data privacy environment nationally. The effects on our business of this growing body of privacy and data protection laws 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 U.S., 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. The EU-US Privacy Shield was such a transfer mechanism put in place by the EU and the U.S., 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”). A replacement of the Privacy Shield – the EU-U.S. Data Privacy Framework (“DPF”) was since developed. In July 2023, the U.S. and EU implemented the DPF. Companies can now use this new mechanism to transfer personal data from the EU to the U.S. and potentially from Switzerland to the U.S., subject to national implementation in Switzerland. The UK Extension to the EU-U.S. Data Privacy Framework (“Data Bridge”) entered into force on October 12, allowing certifying entities to transfer personal data from the UK to the U.S. At the moment, it is unclear whether the anticipated legal challenges against the DPF, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful.

While in July 2020 the CJEU upheld the validity of standard contractual clauses (“SCCs”) as a legal mechanism to transfer personal data to jurisdictions that the European Commission has not found to provide an adequate level of protection and while the European Commission adopted new SCCs in July 2021, companies relying on SCCs must, subject to additional guidance from regulators in the EEA and the U.K., regularly evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. The use of the new SCCs may increase the legal risks and liabilities under EEA privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs and the DPF, any transfers by us or our vendors of personal information from the EEA to the US may not comply with the EEA data protection laws, which may increase our exposure to the GDPR’s heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of EEA personal information outside of the EEA (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products.

The competent authorities and courts in a number of EU Member States increasingly scrutinize and question the GDPR compliance of processing of personal data by US-based entities or entities with links to US-based entities, independently of whether personal data is actually transferred outside the EEA. 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 U.K. and the EU (*i.e.*, following the U.K.’s exit from the EU—otherwise known as Brexit), data processing in the U.K. is governed by a U.K. 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 U.K., on June 28, 2021 the European Commission issued an adequacy decision in respect of the U.K.’s data protection framework, enabling data transfers from EU member states to the U.K. 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, this adequacy decisions will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or unilaterally revoked in the interim 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. In March 2024, the British Government published the Data Protection and Digital Information (No. 2) Bill intended to create a more business-friendly regime in the UK through changes to the existing legislation. At this stage it is unclear whether and when this legislation will be adopted and whether such legislative reforms could potentially lead the European Commission not to extend or to revoke the UK adequacy decision.

If we or our third-party service providers are unable to properly protect the privacy and security of personal information, or other confidential 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 FTC, 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 U.S., 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 laws and regulations frequently being adopted and coming into effect. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our current practices. 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, including 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 absent any findings that we 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 our products and, if approved, product candidates.

The sale of our products, including VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U.S., and the use of our existing product candidates in clinical trials expose 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 products or 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 ourselves against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- delays in or an inability to commercialize VTAMA, and any future products for which we obtain marketing approval;
- 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;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- decreased demand for our VTAMA, and current or future product candidates, 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. We have acquired insurance coverage which extends to liabilities arising from the sale of our products; however, there is no assurance that we will be able to maintain this insurance coverage on commercially reasonable terms or in adequate amounts or that this coverage will be sufficient to cover any losses arising from any claims related to our products or, if approved, product candidates. 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 our products and, if approved, product candidates.

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 limited earthquake and flood insurance coverage, 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, products, product candidates, investigational medicines and the diseases our products, 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 use of AI could expose us to liability or adversely affect our business.

Certain of our early-stage discovery Vants and healthcare technology businesses use machine learning and AI as part of their business. However, there are significant risks involved in utilizing AI and no assurance can be provided that our use of AI will enhance our business or operations or result in our business or operations being more efficient or profitable. For example, AI algorithms may be flawed, insufficient, of poor quality, reflect unwanted forms of bias, or contain other errors or inadequacies, any of which may not be easily detectable; AI has been known to produce false or “hallucinatory” inferences or outputs; AI can present ethical issues and may subject us to new or heightened legal, regulatory, ethical or other challenges; and inappropriate or controversial data practices by developers and end-users, or other factors adversely affecting public opinion of AI, could impair the acceptance of AI solutions, including those incorporated in our businesses. If the AI solutions that we create or use are deficient, inaccurate or controversial, we could suffer from competitive harm, legal liability, brand or reputational harm, or other adverse impacts on our business and financial results. If we do not have sufficient rights to use the data or other material or content on which our AI solutions or other AI tools we use rely, we also may incur liability through the violation of applicable laws, third-party intellectual property, privacy or other rights, or contracts to which we are a party.

In addition, regulation of AI is rapidly evolving worldwide as legislators and regulators are increasingly focused on these powerful emerging technologies. The technologies underlying AI and its uses are subject to a variety of laws, including intellectual property, privacy, data protection and cybersecurity, consumer protection, competition, and equal opportunity laws, and are expected to be subject to increased regulation and new laws or new applications of existing laws. AI is the subject of ongoing review by various U.S. governmental and regulatory agencies, and various U.S. states and other foreign jurisdictions are applying, or are considering applying, their platform moderation, cybersecurity, and data protection laws to AI or are considering general legal frameworks for AI, such as the AI Act currently being considered in the EU. We may not be able to anticipate how to respond to these rapidly evolving frameworks, and we may need to expend resources to adjust our offerings in certain jurisdictions if the legal frameworks are inconsistent across jurisdictions. Furthermore, because AI technology itself is highly complex and rapidly developing, it is not possible to predict all of the legal, operational or technological risks that may arise relating to the use of AI.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology, products 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, products and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our current and future products and product candidates. We seek to protect our proprietary position by in-licensing or acquiring intellectual property and filing patent applications in the U.S. and abroad related to our current and future development programs, products 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 products or product candidates, in whole or in part, and may not effectively prevent others from commercializing competitive products or product candidates, or that an alteration to our products or 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, products 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, our products and, if approved, 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 products and 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 products and, if approved, 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 products or product candidates in the U.S. 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 current and future products or product candidates in the U.S. or in other countries. Our pending PCT patent applications 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 or 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 current and future products and product candidates, 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 products or product candidates or limit the length of terms of patent protection we may have for our products, 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 products or 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 products or, if approved, product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or 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 products or, if approved, product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our products, product candidates or other technologies, competitors and other third parties could market products or 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 products or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future products or product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our products. 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 U.S. may not protect our rights to the same extent as the laws of the U.S., 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 U.S. 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 U.S. 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, products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the U.S., 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 (“IPR”), and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the U.S. 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 U.S. 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, IPR, 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, on April 23, 2024, a petition for an IPR was filed with the Patent Trial and Appeal Board (“PTAB”) by Encube Ethicals Pvt. Ltd., alleging that certain claims of U.S. Patent No. 11,590,088 (the “’088 Patent”), relating to VTAMA (tapinarof) cream 1%, are invalid. The ‘088 Patent expires in 2039. The PTAB is not expected to decide whether to institute the IPR until approximately six months from the petition filing date. In February 2023, Sandoz Group AG filed an opposition challenging Dermavant’s European Patent Number 3297605 which covers topical formulations of tapinarof. The opposition is ongoing and should be decided in the fourth quarter of calendar year 2024.

In addition, certain U.S. patents relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH, as assignee of Genevant Sciences Ltd. (“Genevant”), exclusively licensed from Arbutus Biopharma Corp. (“Arbutus”) have previously been the subject of IPR proceedings brought by Moderna Therapeutics, Inc. (“Moderna”) before the PTAB, whose decisions were subsequently reviewed by the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”). As previously disclosed, the Federal Circuit ultimately affirmed the PTAB’s decisions upholding certain claims under those patents and invalidating others. Additionally, one European patent (EU Patent No. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licensed from Arbutus is the subject of an opposition proceeding brought in 2018 by Merck Sharp & Dohme Corporation and Moderna at the European Patent Office (the “EPO”) Opposition Division. In 2019, the EPO Opposition Division upheld claims as amended by an auxiliary request submitted by the patent owner. Merck and Moderna appealed and, in 2023, the Boards of Appeal of the EPO set aside the EPO Opposition Division decision and remitted the case to the EPO Opposition Division for further prosecution. In March 2024, the EPO Opposition Division issued a preliminary opinion. Oral proceedings are scheduled for June 2024, and the case is pending. Genevant may commence litigation at any time to enforce its patent rights against infringers.

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, products or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or commercialize products and, if approved, 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 products or 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, products and product candidates, or limit the duration of the patent protection of our technology, products 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 products or product candidates but that falls outside the scope of our patent protection. Moreover, patents have a limited lifespan. In the U.S., 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 products and product candidates, it may be open to competition from generic versions of such products or 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 products and product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., 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 or product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, are limited. Even if patents covering products or product candidates are obtained, once the patent life has expired, we may be open to competition from other products or product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new products and product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, the patent covering the use of VTAMA 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 our products and product candidates.

We do not currently and may not in the future own or license any issued composition of matter patents covering certain of our products or product candidates, including VTAMA, and we cannot be certain that any of our other issued patents will provide adequate protection for such products or 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 products and product candidates, such patents may not be available for all of our products and product candidates. For example, we do not own or have a license to any issued composition of matter patents in the U.S. or any other jurisdiction with respect to VTAMA. Instead, we rely on four issued U.S. patents claiming topical formulations of VTAMA, including the commercial formulation which was studied in Phase 3 trials and approved by the FDA, and two issued U.S. patents 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, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We additionally rely on three drug substance (“DS”) patents 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, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We also have a patent covering the use of VTAMA to treat psoriasis wherein patients achieve the Phase 3 clinical endpoints. This method of treatment patent is expected to expire in 2040 (including a potential patent term extension for pediatric exclusivity).

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 products and 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 products and, if approved, 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 U.S. and other countries with respect to our proprietary technology, products, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of products and product candidates, patents protecting our products and product candidates might expire before or shortly after such candidate begins to be commercialized. We expect to seek extensions of patent terms in the U.S. 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 U.S., 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 for a given product or product candidate.

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 preclinical 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 current and future products and product candidates, 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 products and 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 commercialize products and develop and eventually, if approved, 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 and future products and 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 products and 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, products or 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 products and product candidates. If our licenses are terminated, we may lose our rights to develop and market our technology, products and product candidates, lose patent protection for our products, product candidates and technology, experience significant delays in the development and commercialization of our products and 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 products and 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 products and 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 products or 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. 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 products and 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, products 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 IMVT-1402 or file or enforce patents relating to these assets in territories other than the U.S., 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 VTAMA in China, including Hong Kong, Macau or Taiwan, as such rights were retained by Welichem Biotech Inc. or licensed to third parties. 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 current and future products and product candidates.

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 products or 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 U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, IPR 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 products, 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 products or product candidates. 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 products or 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 products or product candidates, the holders of any such patents may be able to block our ability to commercialize such products or, if approved, product candidates, 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 or, if approved, 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 products or, if approved, 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 products or 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 products or, if approved, 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 products or, if approved, 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 products or 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 financial and other 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 products or, if approved, product candidates. 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 products and 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 U.S. and abroad that is or may be relevant to or necessary for the commercialization of products or product candidates in any jurisdiction. Patent applications in the U.S. 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 U.S. remain confidential until patents issue. Therefore, patent applications covering our products and 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 current and future products and product candidates, or the use thereof, provided such pending patent applications result in issued patents. Our ability to develop and market our current and future products and product candidate 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 products or, if approved, product candidates. We may incorrectly determine that our products or 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 U.S. 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 current and future products and, if approved, product candidates.

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 products or, if approved, product candidates, that are held to be infringing. We might, if possible, also be forced to redesign products or product candidates 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. For example, in February 2022, Roivant's subsidiary, Genevant Sciences GmbH ("Genevant GmbH"), and Arbutus filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna and an affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19 (the "Moderna Action"). In November 2022, the District Court denied Moderna's partial motion to dismiss pursuant to 28 U.S.C. § 1498(a) ("§ 1498"). In March 2023, following the submission of a Statement of Interest in the case by the U.S. Government, the court reaffirmed its prior decision and again ruled that the complaint should not be partially dismissed on the basis of § 1498. On February 8, 2024, the court held a Claim Construction hearing on disputed terms within the claims of the asserted patents. On April 3, 2024, the court provided its Claim Construction ruling, in which it construed the disputed claim terms and agreed with Genevant GmbH and Arbutus' position on most of the disputed claim terms. Fact discovery is on-going and next steps include expert reports and depositions. A trial date has been set for April 21, 2025. On April 4, 2023, Genevant GmbH and Arbutus filed a lawsuit in the U.S. District Court for the District of New Jersey against Pfizer and BioNTech seeking damages for infringement of U.S. Patent Nos. 9,504,651, 8,492,359, 11,141,378, 11,298,320 and 11,318,098 in the manufacture and sale of COMIRNATY (the "Pfizer Action"). On July 10, 2023, Pfizer and BioNTech filed an answer. The Pfizer Action is ongoing and a date for a claim construction hearing has not been set.

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 and if any such suits, including the Moderna Action and the Pfizer Action, will ultimately be resolved successfully. 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 U.S., 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, IPR or post-grant review, or oppositions or similar proceedings outside the U.S., 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 products or 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, we may not seek, or 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 U.S. 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 the Moderna Action, the Pfizer Action or any other 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. 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 or have licensed are owned or licensed 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 or have licensed are assigned to or licensed by our direct or indirect subsidiaries. For example, any patents that Immunovant has licensed are assigned to its wholly-owned subsidiary Immunovant Sciences GmbH and any patents that Dermavant owns or has licensed 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 U.S. 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 products and 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 U.S. or USPTO rules and regulations could increase the uncertainties and costs.

The U.S. 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, in June 2022, the World Trade Organization members agreed to waive certain 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 U.S. 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 U.S. 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 acquired or in-licensed patent rights and technology for certain products or 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 products or product candidates embodying such inventions in the U.S. 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 products or product candidates, or patents that cover our biologic product candidates, can be challenged by third parties.

If a third party files an application under Section 505(b)(2) or an abbreviated new drug application (“ANDA”) under Section 505(j) with respect to any of our products or, if approved, product candidates, for a generic product containing any of our products or product candidates, including VTAMA, 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 product or, if 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 product or, if 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 issued U.S. patents covering VTAMA 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 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 VTAMA and successfully challenging the validity of the patents or successfully designing around the patents. Any successful challenge against the patents and/or designing around one or more of the patents could result in a generic version of VTAMA being commercialized before the expiration of the patents. If the 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 our products and product candidates.

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

Filing, prosecuting and defending patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing product candidates made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and product candidates and may also export infringing products and product candidates to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These product candidates may compete with our products or 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 products and product candidates and services that are the same as or similar to our products and product candidates, 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 products and product candidates, which could make it difficult for us to stop the infringement of our patents or marketing of competing products or 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 our products and 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 current and future products and product candidates, and we collaborate and expect to continue to collaborate with third parties on the development of current and future products and 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 U.S. 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 U.S. 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, products and product candidates and could result in our inability to develop, manufacture or commercialize our products and 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 products and 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 our products and 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 our products or 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, including the Moderna Action and the Pfizer Action, 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 pursue our commercialization efforts, 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 pursue our commercialization efforts, continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our products or, if approved, product candidates. 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 our products from the products and product candidates of our competitors. Our current and future trademark applications in the U.S. 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 products or 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, IPR, 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 our products or 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 our products or 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 U.S. 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 products, 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

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, 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. 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;
- receipt of marketing approval for a product or product candidate in one or more jurisdictions, or the failure to receive such marketing approval;
- the results of clinical trials or preclinical 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;
- the outcome of litigation or other claims or proceedings, including governmental and regulatory proceedings, against us or the Vants;
- 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 and the relatively limited free float of our common shares;
- any significant change in our board of directors or management;
- sales of substantial amounts of our common shares by 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 incurred and will continue to incur increased costs as a result of operating as a public company and our management has devoted and will continue to devote a substantial amount of time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses are expected to increase from March 31, 2024, after which date we were no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. 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. We also expect that compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and increased disclosure requirements will substantially increase our legal and financial compliance costs. Our management and other personnel have devoted 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 blended director and officer liability insurance and forced us to forego securities and corporate protection coverage. We cannot predict or estimate the amount or timing of additional costs we have incurred 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.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common shares may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting, and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and costly. If we or our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common shares may decline.

Although we have determined that our internal control over financial reporting was effective as of March 31, 2024, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could adversely impact our ability to accurately and timely report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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, as well as provisions of 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; 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 own a significant percentage of our common shares and are able to exert significant control over matters subject to shareholder approval.

Our largest shareholders continue to 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 they may exercise their 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. Furthermore, our largest shareholders may from time to time have interests that differ from ours or from one another, and from time to time there may be disputes with or between such shareholders, which could be costly, time-consuming and divert management resources. So long as these holders continue to own a significant amount of our equity, they will continue to be able to strongly influence 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 may need additional capital in the future to continue our 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 securities, including 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, restricted stock units and other share-based awards to our employees, directors and consultants. The aggregate number of shares initially reserved for issuance under the 2021 EIP increases 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, restricted stock units 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.

Future sales, or the perception of future sales, of our common shares by us or our existing shareholders could cause the market price for our common shares to decline and impact our ability to raise capital in the future.

Sales of a substantial number of our common shares by us or certain of our existing large shareholders, or the perception that these sales could occur, could substantially decrease the market price of our common shares. Shares held by certain of our large shareholders have been registered for re-sale pursuant to a registration statement on Form S-3 and may also be sold pursuant to Rule 144 under the Securities Act, subject to certain restrictions (including restrictions applicable to affiliates in the case of shares held by persons deemed to be our affiliates). The market price of our common shares could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. This, in turn, could also make it more difficult for us to raise additional funds through future offerings of our common shares or other securities at prices that are attractive to us, or at all.

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.

Because there are no 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.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no 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. 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, including as a result of the denial of treaty benefits that we may claim. 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 and are centrally managed and controlled in the UK. We currently have subsidiaries in the U.S., U.K., Switzerland 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 between two or more affiliated companies, they could require such affiliated companies to adjust their transfer prices and thereby reallocate the income between such affiliated companies 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 (including tax treaties), 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 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 (including tax treaties) or the interpretation of such tax laws (including tax treaties) and changes in U.S. generally accepted accounting principles; (7) challenges to the transfer pricing policies related to our structure; (8) potential taxation under the OECD BEPS 2.0; and (9) potential limitation on tax attributes due to ownership changes (i.e. Internal Revenue Code 382 and 383) or expiration.

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 were not classified as a CFC for the taxable year ended March 31, 2024. However, our non-U.S. subsidiaries will be classified as CFCs for the taxable year ended March 31, 2024. 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, if we own (directly or indirectly) at least 25% (by value) of the stock of another corporation, for purposes of determining whether we are a PFIC, generally we would be treated as if we held our proportionate share of the assets of such other corporation and received directly our proportionate share of the income of such other corporation and generally we would retain the character of such assets and income as if they were held directly by us rather than by such other corporation. 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. Because our common shares should be considered to be "publicly traded" for the taxable year that ended on March 31, 2024, we would apply the 50% passive asset test using the fair market value of our assets. 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, 2024, we believe that we were not a PFIC based in part upon the fair market value of our assets, including any goodwill and intangible property, and the nature and composition of our income and assets.

Our status as a PFIC is a fact-intensive determination made on an annual basis, which is subject to uncertainties, including but not limited to the fact that the value of our assets for purposes of the PFIC determination may be affected by the trading value of our common shares, which could fluctuate significantly. The total value of our assets for purposes of the PFIC asset test frequently (though not invariably) may be inferred using the market price of our ordinary shares, which may fluctuate considerably and thereby affect the determination of our PFIC status for 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 endeavor to determine our PFIC status for each taxable year and make such determination available to U.S. holders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

Roivant's corporate information security organization, led by our Chief Information Security Officer ("CISO"), is responsible for our overall information security strategy, policy, security engineering, operations and cybersecurity threat and incident detection and response centrally at Roivant and the majority of our Vants. Certain of our Vants, including Immunovant, Dermavant and our healthcare technology Vants, have established and maintain separate cybersecurity functions which are similarly designed to protect their information and assets from cybersecurity threats or incidents.

Roivant and the Vants' information security organization manages a robust enterprise security structure with the goal of preventing and mitigating any cybersecurity incidents, while simultaneously working to continually increase information technology system resilience designed to minimize any business impact should a cybersecurity incident occur. Central to Roivant's information security organization is our Cybersecurity Incident Response Team, which is responsible for the protection, detection and response capabilities used to protect our data and enterprise computing networks. A Cybersecurity Risk Governance Committee oversees processes for identifying and mitigating cybersecurity threats and incidents and helps align our risk exposure with our strategic objectives. Cybersecurity threats and incidents deemed to have a moderate or higher business impact, even if immaterial to us as a whole, are reported to the Corporate Risk Management Committee and shared with Roivant's board of directors.

Roivant and the Vants implement multiple levels of cybersecurity measures, including standard malware detection and prevention software, email security programs, privileged access management, vulnerability detection and remediation software, security patching management, security event logging and reviews and special isolation and access controls for data repositories that may contain sensitive information, including protected health information.

Roivant and the Vants' cybersecurity programs are informed by industry standards and includes periodic risk assessments and security testing supported by cybersecurity technologies, including third-party security solutions, vulnerability management, and monitoring tools, designed to monitor, identify and manage risks from cybersecurity threats and incidents. In addition, we have implemented employee security and awareness training related to cybersecurity threats and incidents.

Roivant and the Vants undergo periodic internal compliance audits and external reviews to evaluate our controls, including cybersecurity controls. Additionally, a majority of our information technology systems are built on services provided by third parties. In an effort to minimize third-party risk, we have established a process designed to assess the cybersecurity practices of third-party suppliers and related risks, including through review of relevant supplier certifications and cybersecurity procedures and responses to standardized information-gathering questionnaires, as we deem applicable and appropriate. Our control over and ability to monitor the security posture of third parties with whom we do business remains limited and there can be no assurance that we can prevent, mitigate or remediate the risk of any compromise or failure in the security infrastructure owned or controlled by such third parties. Additionally, any contractual protections with such third parties, including our right to indemnification, if any at all, may be limited or insufficient to prevent a negative impact on our business from any such compromise or failure.

Governance Related to Cybersecurity Risks

Roivant's board of directors oversees our overall risk management strategy, including with respect to cybersecurity risks. Cybersecurity risk management policies and procedures are integrated into our overall risk management strategy, which is overseen by the audit committee of the board of directors ("Audit Committee"). At least annually, the Audit Committee discusses our risk management program, including any information security and technology risks and findings from any audits, with our internal audit staff, including our Chief Accounting Officer.

At the management level, our CISO is primarily responsible for leading our cybersecurity strategy centrally at Roivant and the majority of our Vants. Our CISO has extensive cybersecurity experience across a wide array of industries, with previous leadership positions specializing in safeguarding healthcare data across various health technology companies.

At Immunovant, Dermavant and the healthcare technology Vants that have established and maintain separate cybersecurity functions, governance is similarly overseen in the first instance by the boards of directors of those Vants as part of their overall risk management strategy, with ultimate oversight on a company-wide basis by the Roivant board of directors.

ITEM 2. PROPERTIES

Our principal executive offices are located at 7th Floor, 50 Broadway, London SW1H 0DB, United Kingdom. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. Certain of our subsidiaries and affiliates also have business operations in New York, New York and Basel, Switzerland.

Our subsidiary Roivant Sciences, Inc. subleases 83,340 square feet of office space located in New York, New York, pursuant to a sublease agreement that expires in October 2032. Certain of our subsidiaries and affiliates also lease office space in New York, New York and Basel, Switzerland. We do not own any properties.

We believe that our and our subsidiaries' leased facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in legal or regulatory proceedings arising in the ordinary course of our business. We do not currently, however, expect any such legal proceedings to have a material adverse effect on our business, operating results or financial condition. However, depending on the nature and timing of a given dispute, an unfavorable resolution could materially affect our current or future results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common shares are listed on the Nasdaq Global Select Market under the symbol "ROIV."

Holders

As of May 28, 2024, there were approximately 70 holders of record of our common shares. The actual number of holders of our common shares is greater than this number of record holders and includes shareholders who are beneficial owners but whose common shares are held in street name by banks, brokers and other nominees.

Dividend Policy

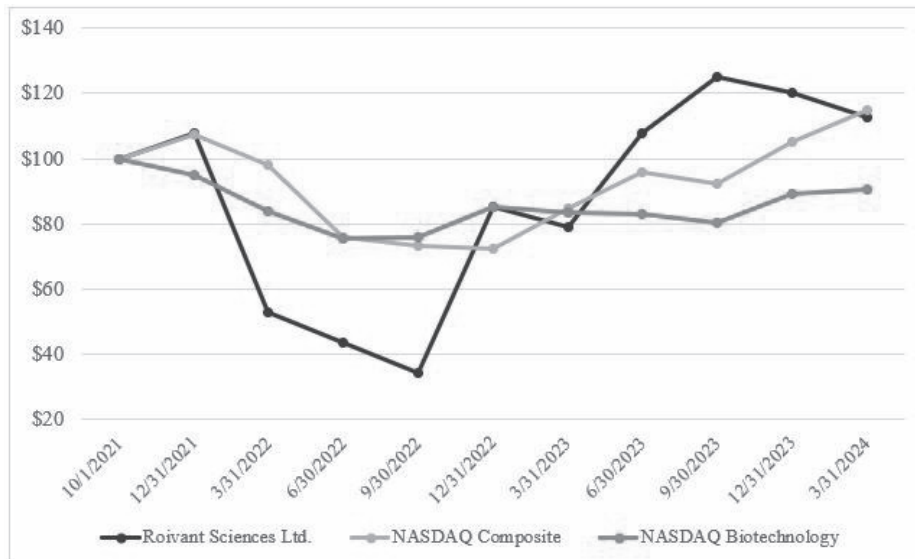
We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated herein by reference.

Performance Graph

The following stock performance graph illustrates a comparison from October 1, 2021 (the date our common shares commenced trading on the Nasdaq Global Market) through March 31, 2024, of the total cumulative shareholder return on our common shares, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. This graph assumes an initial investment of \$100 on October 1, 2021 at the market closing price of \$9.35 per share, and that all dividends were reinvested (although dividends have not been paid on our common shares). The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common shares.



The information included under the heading Performance Graph is “furnished” and not “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be “soliciting material” subject to Regulation 14A or incorporated by reference in any filing under the Securities Act or the Exchange Act.

Sales of Unregistered Securities and Use of Proceeds

None.

Issuer Repurchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. 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 consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K. 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 “Forward-Looking Statements” and “Risk Factors” in this Annual Report on Form 10-K. Our fiscal year ends on March 31 and our fiscal quarters end on June 30, September 30 and December 31.

Overview

Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant’s pipeline is concentrated in inflammation and immunology and includes VTAMA, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting the neonatal Fc receptor (“FcRn”) in development across several IgG-mediated autoimmune indications; and brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 for the treatment of dermatomyositis and non-infectious uveitis, in addition to several other therapies in various stages of clinical development. We advance our pipeline by creating nimble subsidiaries or “Vants” to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business.

Components of Results of Operations

Product revenue, net

With the FDA approval of VTAMA for the treatment of plaque psoriasis in adult patients and our initial product launch in May 2022, we began to recognize product revenues. We record product revenue net of estimated chargebacks, discounts, rebates, returns, and other allowances associated with the respective sales.

License, milestone and other revenue

License, milestone and other revenue includes the recognition of payments received in connection with license agreements as well as revenue generated by subscription and service-based fees.

Cost of revenues

We began to recognize cost of product revenues after the initial product launch of VTAMA in May 2022. Cost of product revenues includes the cost of producing and distributing inventories related to product revenue during the respective period, including manufacturing, freight, and indirect overhead costs. Additionally, milestone payments made in connection with regulatory approvals and sales-based milestones are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Our cost of revenues also 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.

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 contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of our product candidates.
- Unallocated internal costs, including:
 - employee-related expenses, such as salaries, share-based compensation, and benefits, for research and development personnel; and
 - other expenses that are not allocated to a specific program.

Research and development activities 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 and our recently in-licensed assets through preclinical studies and clinical trials, as well as acquire or discover new product candidates. We expect higher employee-related expenses, including 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 or other epidemics; and
- our ability to maintain a continued acceptable safety profile of our product candidates following approval of our product candidates.

The successful development of our product candidates is highly uncertain, and we cannot reasonably estimate the costs that will be necessary to complete the remainder of the development 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.

Acquired in-process research and development expenses

Acquired in-process research and development (“IPR&D”) expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

Consideration for the purchase of IPR&D through asset acquisitions and license agreements may include cash upfront payments, shares and other liability instruments issued, and the fair value of future contingent consideration payments.

Selling, general and administrative expenses

Selling, general and administrative (“SG&A”) expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, sales incentive compensation, and benefits, for employees engaged in SG&A activities. SG&A employees include those responsible for the identification and acquisition or in-license of new drug candidates as well as for managing Vant operations and facilitating the use of our platform and technologies at the Vants. SG&A expenses also consist of marketing programs, advertising, legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations.

We expect SG&A expenses to increase in future periods as we continue to expand our sales and marketing infrastructure and general administrative functions. These increases will likely include salaries, sales incentive compensation, share-based compensation and travel expenses associated with our sales force, which began promoting VTAMA in the U.S. following approval by the FDA in May 2022, as well as expected costs associated with the further build out of our commercial operations functions. We anticipate these expenses to further increase if any of our other current or future product candidates receives regulatory approval in the U.S. or another jurisdiction.

Gain on sale of Telavant net assets

Gain on sale of Telavant net assets represents the gain resulting from the sale of our entire equity interest in our majority-owned subsidiary, Telavant Holdings, Inc. (“Telavant”), to Roche Holdings, Inc. (“Roche”) in December 2023 (the “Roche Transaction”). Prior to the Roche Transaction, we held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer Inc. owned the remaining 25%, in each case on an as-converted basis. At closing, we received approximately \$5.2 billion in cash. We are also eligible to receive an additional one-time milestone payment of approximately \$110 million if the milestone payment condition is satisfied. Refer to Note 6, “Recent Transactions” of our financial statements for further information regarding the Roche Transaction.

Change in fair value of investments

Change in fair value of investments primarily includes the unrealized loss on equity investments in publicly-traded companies, including Arbutus Biopharma Corporation (“Arbutus”), as well as our equity investment in Heracles Parent, L.L.C. (“Datavant”). We have elected the fair value option to account for these investments.

Change in fair value of debt and liability instruments

Change in fair value of debt and liability instruments primarily includes the 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 Sciences Ltd. (“Dermavant”) to NovaQuest Co-Investment Fund VIII, L.P. (the “NovaQuest Facility”), and other liability instruments, including warrant liabilities, prior to their redemption, and earn-out share liabilities issued in connection with our business combination (the “Business Combination”) with Montes Archimedes Acquisition Corp. (“MAAC”), a special purpose acquisition company. Refer to Note 15, “Earn-Out Shares, Public Warrants and Private Placement Warrants” of our financial statements for further information regarding the redemption of our warrants.

Gain on deconsolidation of subsidiaries

Gain on deconsolidation of subsidiaries resulted from the determination that we no longer had a controlling financial interest in certain subsidiaries.

Interest income

Interest income consists of interest earned on our cash equivalents.

Interest expense

Interest expense results from interest accrued on long-term debt and the amortization of debt discount and issuance costs.

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 years ended March 31, 2024 and 2023

The following table sets forth our results of operations for the years ended March 31, 2024 and 2023:

	Years Ended March 31,		Change
	2024	2023	
	<i>(in thousands)</i>		
Revenues:			
Product revenue, net	\$ 75,057	\$ 28,011	\$ 47,046
License, milestone and other revenue	49,738	33,269	16,469
Revenue, net	<u>124,795</u>	<u>61,280</u>	<u>\$ 63,515</u>
Operating expenses:			
Cost of revenues	15,560	13,128	2,432
Research and development	501,736	525,215	(23,479)
Acquired in-process research and development	26,450	97,749	(71,299)
Selling, general and administrative	687,443	600,506	86,937
Total operating expenses	<u>1,231,189</u>	<u>1,236,598</u>	<u>(5,409)</u>
Gain on sale of Telavant net assets	5,348,410	—	5,348,410
Income (loss) from operations	<u>4,242,016</u>	<u>(1,175,318)</u>	<u>5,417,334</u>
Change in fair value of investments	47,973	20,815	27,158
Change in fair value of debt and liability instruments	78,943	78,001	942
Gain on deconsolidation of subsidiaries	(32,772)	(29,276)	(3,496)
Interest income	(146,425)	(32,184)	(114,241)
Interest expense	34,778	27,968	6,810
Other expense (income), net	6,089	(15,808)	21,897
Income (loss) from continuing operations before income taxes	4,253,430	(1,224,834)	5,478,264
Income tax expense	22,224	5,190	17,034
Income (loss) from continuing operations, net of tax	<u>4,231,206</u>	<u>(1,230,024)</u>	<u>5,461,230</u>
Income from discontinued operations, net of tax	—	114,561	(114,561)
Net income (loss)	<u>4,231,206</u>	<u>(1,115,463)</u>	<u>5,346,669</u>
Net loss attributable to noncontrolling interests	(117,720)	(106,433)	(11,287)
Net income (loss) attributable to Roivant Sciences Ltd.	<u>\$ 4,348,926</u>	<u>\$ (1,009,030)</u>	<u>\$ 5,357,956</u>

Variance analysis for years ended March 31, 2024 and 2023

Product revenue, net

	Years Ended March 31,		Change
	2024	2023	
	<i>(in thousands)</i>		
Product revenue, net	\$ 75,057	\$ 28,011	\$ 47,046

Product revenue, net increased by \$47.0 million to \$75.1 million for the year ended March 31, 2024, compared to \$28.0 million for the year ended March 31, 2023, primarily due to higher units sold. Product revenue, net consists of net product revenues from VTAMA sales, following the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022.

License, milestone and other revenue

	Years Ended March 31,		Change
	2024	2023	
	(in thousands)		
License, milestone and other revenue	\$ 49,738	\$ 33,269	\$ 16,469

License, milestone and other revenue increased by \$16.5 million to \$49.7 million for the year ended March 31, 2024, compared to \$33.3 million for the year ended March 31, 2023. The increase was primarily driven by \$15.0 million of revenue relating to milestone income at Dermavant pursuant to a collaboration and license agreement with Japan Tobacco Inc. during the year ended March 31, 2024.

Cost of revenues

For the years ended March 31, 2024 and 2023, our cost of revenues consisted of the following:

	Years Ended March 31,		Change
	2024	2023	
	(in thousands)		
Cost of product and other revenues	\$ 5,928	\$ 5,660	\$ 268
Amortization of intangible assets	9,632	7,468	2,164
Cost of revenues	\$ 15,560	\$ 13,128	\$ 2,432

Cost of revenues increased by \$2.4 million to \$15.6 million for the year ended March 31, 2024, compared to \$13.1 million for the year ended March 31, 2023. During the year ended March 31, 2024 and 2023, cost of revenues included \$3.4 million and \$1.8 million, respectively, of costs relating to VTAMA sales. Cost of revenues additionally included amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022.

Research and development expenses

For the years ended March 31, 2024 and 2023, our research and development expenses consisted of the following:

	Years Ended March 31,		Change
	2024	2023 ⁽¹⁾	
	(in thousands)		
<i>Program-specific costs:</i>			
Batoclimab ⁽¹⁾	\$ 74,265	\$ 78,477	\$ (4,212)
IMVT-1402 ⁽¹⁾	43,102	10,270	32,832
Brepocitinib	38,563	38,627	(64)
RVT-3101	35,129	7,559	27,570
Tapinarof	34,256	45,201	(10,945)
Namilumab	13,236	11,757	1,479
RVT-2001	10,132	16,075	(5,943)
Other development and discovery programs	39,767	122,877	(83,110)
Total program-specific costs	288,450	330,843	(42,393)
<i>Unallocated internal costs:</i>			
Share-based compensation	34,595	30,914	3,681
Personnel-related expenses	136,425	131,908	4,517
Other expenses	42,266	31,550	10,716
Total research and development expenses	\$ 501,736	\$ 525,215	\$ (23,479)

⁽¹⁾ Certain prior period amounts have been reclassified to conform to current period presentation.

Research and development expenses decreased by \$23.5 million to \$501.7 million for the year ended March 31, 2024, compared to \$525.2 million for the year ended March 31, 2023, primarily due to a decrease in program-specific costs of \$42.4 million, partially offset by increases in other expenses of \$10.7 million, personnel-related expenses of \$4.5 million, and share-based compensation of \$3.7 million.

The decrease of \$42.4 million in program-specific costs was primarily driven by a decrease of \$83.1 million in other development and discovery program expense, which in part resulted from the deconsolidation of Proteovant Sciences, Inc. (“Proteovant”) in August 2023 along with the reprioritization of certain programs and drug discovery efforts. This decrease was partially offset by increases of \$32.8 million relating to IMVT-1402 and \$27.6 million relating to RVT-3101, which was acquired in November 2022. The rights to further develop and manufacture RVT-3101 were sold to Roche in December 2023.

Acquired in-process research and development expenses

	Years Ended March 31,		Change
	2024	2023	
	<i>(in thousands)</i>		
Consideration for the purchase of IPR&D	\$ 13,950	\$ 87,749	\$ (73,799)
Development milestone payments	12,500	10,000	2,500
Total acquired in-process research and development expenses	\$ 26,450	\$ 97,749	\$ (71,299)

Acquired in-process research and development expenses decreased by \$71.3 million to \$26.5 million for the year ended March 31, 2024, compared to \$97.7 million for the year ended March 31, 2023. The decrease was primarily due to higher consideration for the purchase of IPR&D during the year ended March 31, 2023 as a result of consideration for the purchase of IPR&D of \$87.7 million relating to the acquisition of RVT-3101 in November 2022 and the achievement of a development milestone relating to batoclimab, which resulted in a one-time milestone expense of \$10.0 million. Acquired in-process research and development expenses for the year ended March 31, 2024 was driven by \$14.0 million of consideration for the purchase of IPR&D relating to an asset acquisition completed by a newly-formed subsidiary and \$12.5 million relating to the achievement of development and regulatory milestones for batoclimab.

Selling, general and administrative expenses

	Years Ended March 31,		Change
	2024	2023	
	<i>(in thousands)</i>		
Selling, general and administrative	\$ 687,443	\$ 600,506	\$ 86,937

Selling, general and administrative expenses increased by \$86.9 million to \$687.4 million for the year ended March 31, 2024, compared to \$600.5 million for the year ended March 31, 2023. The increase was primarily due to an increase in selling, general and administrative expenses of \$55.7 million at Dermavant as a result of the progression of the commercial launch of VTAMA and an increase in personnel-related expenses of \$25.1 million, primarily as a result of a special one-time cash retention bonus award granted to employees.

Gain on sale of Telavant net assets

	Years Ended March 31,		Change
	2024	2023	
	<i>(in thousands)</i>		
Gain on sale of Telavant net assets	\$ 5,348,410	\$ —	\$ 5,348,410

Gain on sale of Telavant net assets was approximately \$5.3 billion for the year ended March 31, 2024 and resulted from the sale of our entire equity interest in Telavant to Roche in December 2023. At closing, we received approximately \$5.2 billion in cash for our pro rata portion of the consideration. Additionally, we derecognized the carrying amount of noncontrolling interest in Telavant of \$87.5 million and transferred net liabilities of \$26.5 million. This resulted in a gain of approximately \$5.3 billion. Refer to Note 6, “Recent Transactions” of our audited financial statements for further information regarding the Roche Transaction.

Change in fair value of investments

	Years Ended March 31,		Change
	2024	2023	
		(in thousands)	
Change in fair value of investments	\$ 47,973	\$ 20,815	\$ 27,158

Change in fair value of investments were unrealized losses of \$48.0 million and \$20.8 million for the years ended March 31, 2024 and 2023, respectively. The change of \$27.2 million was primarily driven by changes in the public share prices of our equity investments, including Arbutus, as well as the change in fair value of our investment in Datavant.

Change in fair value of debt and liability instruments

	Years Ended March 31,		Change
	2024	2023	
		(in thousands)	
Change in fair value of debt and liability instruments	\$ 78,943	\$ 78,001	\$ 942

Change in fair value of debt and liability instruments were losses of \$78.9 million and \$78.0 million for the years ended March 31, 2024 and 2023, respectively. Change in fair value of debt and liability instruments for the year ended March 31, 2024 primarily consisted of a loss of \$46.1 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination and a loss of \$32.1 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 year ended March 31, 2023 primarily consisted of a loss of \$59.6 million relating to the NovaQuest facility, which was primarily due to the impact of VTAMA approval in psoriasis, and a loss of \$24.1 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination.

Gain on deconsolidation of subsidiaries

	Years Ended March 31,		Change
	2024	2023	
		(in thousands)	
Gain on deconsolidation of subsidiaries	\$ (32,772)	\$ (29,276)	\$ (3,496)

Gain on deconsolidation of subsidiaries was \$32.8 million for the year ended March 31, 2024 and resulted from the deconsolidation of certain subsidiaries, including VantAI Holdings, Inc. ("VantAI") in July 2023 and Proteovant in August 2023.

Gain on deconsolidation of subsidiaries was \$29.3 million for the year ended March 31, 2023 and resulted from the deconsolidation of certain subsidiaries in November 2022 and July 2022.

Interest income

	Years Ended March 31,		Change
	2024	2023	
		(in thousands)	
Interest income	\$ (146,425)	\$ (32,184)	\$ (114,241)

Interest income increased by \$114.2 million to \$146.4 million for the year ended March 31, 2024, compared to \$32.2 million for the year ended March 31, 2023. This increase is primarily due to higher cash balances in our interest-bearing cash accounts as well as higher interest rates.

Interest expense

	Years Ended March 31,		Change
	2024	2023	
		(in thousands)	
Interest expense	\$ 34,778	\$ 27,968	\$ 6,810

Interest expense increased by \$6.8 million to \$34.8 million for the year ended March 31, 2024, compared to \$28.0 million for the year ended March 31, 2023. The increase primarily resulted from Dermavant's revenue interest purchase and sale agreement (the "RIPSA"), pursuant to which funding of \$160.0 million was received in June 2022 following the approval of VTAMA by the FDA in May 2022.

Income from discontinued operations, net of tax

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2024</u>	<u>2023</u>	
	<i>(in thousands)</i>		
Income from discontinued operations, net of tax	\$ —	\$ 114,561	\$ (114,561)

Income from discontinued operations, net of tax was \$114.6 million for the year ended March 31, 2023 and resulted from the gain on sale of common shares of Myovant Sciences Ltd. (the "Myovant Top-Up Shares") after Sumitovant Biopharma Ltd.'s ("Sumitovant") acquisition of Myovant Sciences Ltd. ("Myovant") in March 2023. We were entitled to the Myovant Top-Up Shares pursuant to the December 2019 transaction with Sumitomo Pharma Co., Ltd. (the "Sumitomo Transaction") that included, among other things, the transfer of our ownership interest in five Vants to Sumitovant. The Sumitomo Transaction was presented as discontinued operations during the year ending March 31, 2020, and the right to receive the Myovant Top-Up Shares was treated as a contingent consideration upon a sale of the business and accounted for as a gain contingency. Refer to Note 9, "Discontinued Operations" of our audited financial statements for additional information.

Liquidity and Capital Resources

For the years ended March 31, 2024 and 2023, we had income from continuing operations of approximately \$4.2 billion and incurred a loss from continuing operations of approximately \$1.2 billion, respectively. As of March 31, 2024, we had cash and cash equivalents of approximately \$6.5 billion and our retained earnings was approximately \$576.2 million. Through our subsidiary Dermavant, we launched our first commercial product, VTAMA, following approval by the FDA in May 2022. We began generating product revenue, net from sales of VTAMA in the U.S. in May 2022. We also have generated revenue through license agreements as well as from subscription and service-based fees.

Our short-term and long-term liquidity requirements as of March 31, 2024 included:

- contractual payments related to our long-term debt (see Note 8, "Long-Term Debt" and Note 18, "Subsequent Events" of our audited financial statements);
- obligations under our leases (see Note 13, "Leases" of our audited financial statements);
- certain commitments to Samsung Biologics Co., Ltd. ("Samsung") pursuant to a Product Service Agreement entered between Immunovant and Samsung by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. Immunovant had the right to terminate the PSA with 30 days' written notice to Samsung, exercisable no later than January 2024, in the event Immunovant decided to stop all development of, and all attempts to obtain regulatory approval for, batoclimab; subject to payment to Samsung of non-cancelable service fees and costs incurred by Samsung for all batches of batoclimab scheduled to be manufactured during the two-year period following such termination. Because efforts to develop and obtain regulatory approval for batoclimab remain ongoing, Immunovant did not exercise that early termination right and it has lapsed. As a result, Immunovant has an additional minimum obligation to purchase additional batches of batoclimab in the four-year period of 2026 through 2029. As of March 31, 2024, the remaining minimum purchase commitment related to this agreement was estimated to be approximately \$46.2 million; and
- certain commitments to GSK pursuant to a commercial supply agreement entered between Dermavant and GSK. In conjunction with Dermavant's entry into the GSK Agreement in 2018, Dermavant entered into a clinical supply agreement pursuant to which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during our clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and prices. The commercial supply agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, Dermavant and GSK amended the terms of the clinical supply and commercial supply agreements which released GSK of certain commitments to supply tapinarof and released Dermavant of certain commitments to purchase tapinarof in exchange for a supplementary fee. Other supply and purchase commitments under the agreements remain in effect. In addition, Dermavant and Thermo Fisher Scientific ("TFS") entered into a Commercial Manufacturing and Supply Agreement for which TFS agreed to provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. The minimum purchase commitment related to these agreements was estimated to be approximately \$33.3 million.

The above purchase commitments do not represent all of our anticipated purchases, but instead represent only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Additionally, 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 the amount, timing, and likelihood of such payments are not known. We will also be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements.

Potential material future milestone payments as of March 31, 2024 pursuant to certain key asset acquisition and license agreements are as follows:

- **VTAMA/tapinarof (Dermavant):** up to CAD\$75.0 million in remaining commercial milestones to Welichem Biotech Inc., with CAD\$35.0 million payable upon VTAMA first U.S. commercial sale for atopic dermatitis and the remainder payable as first commercial sales are achieved in various countries outside of the U.S. Additional milestones are owed to NovaQuest pursuant to the NovaQuest Agreement. Refer to Note 8, "Long-Term Debt" and Note 18, "Subsequent Events" of our audited financials for further information.
- **Anti-FcRn franchise (Immunovant):** up to a maximum of \$420.0 million to HanAll Biopharma Co., Ltd. upon the achievement of certain development, regulatory and sales milestone events.
- **Brepocitinib (Priovant Therapeutics, Inc.):** mid tens-of-millions sales milestone payment to Pfizer if aggregate net sales in a given year exceed a mid-hundred-of-millions amount.
- **Namilumab (Kinevant Ltd.):** up to approximately \$40 million to the prior shareholders of Izana Biosciences Limited upon the achievement of certain milestones.

Royalties are also due on net sales pursuant to these agreements. The Company has further commitments not reflected above relating to other asset acquisition and license agreements entered and expects to enter into additional asset acquisition and license agreements in the future, which may require upfront payments and long-term commitments of capital resources.

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 board of directors has authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to \$1.5 billion (excluding fees and expenses). The repurchase program is funded by available cash and cash equivalents on hand and does not have an expiration date. Pursuant to the share repurchase program, on April 2, 2024, we entered into a share repurchase agreement with Sumitomo to repurchase all 71,251,083 common shares held by Sumitomo at a purchase price per share of \$9.10, for an aggregate purchase price of approximately \$648.4 million. The repurchase transaction with Sumitomo was completed on April 2, 2024.

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.

RSL Equity Financing Transactions

Since inception, we have completed multiple equity financing transactions, including the following:

In December 2019, together with Sumitomo Pharma Co., Ltd. ("Sumitomo"), we completed the transactions contemplated by the transaction agreement by and between us and Sumitomo, dated as of October 31, 2019. In connection with the Sumitomo Transaction, we raised net proceeds of approximately \$999.2 million due to 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 entered into subscription agreements with certain investors, whereby we issued 22,000,000 of our common shares at \$10.00 per share for an aggregate purchase price of \$220.0 million (the "PIPE Financing"). In connection with the Business Combination and PIPE Financing, we received approximately \$213.4 million in cash at closing.

In September 2022, we entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell our common shares having an aggregate offering price of up to \$400.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as our agent (the "ATM Facility"). As of March 31, 2024, we had \$400.0 million of remaining capacity available under the ATM Facility.

In November 2022, we completed an underwritten primary and secondary public offering of 30,000,000 of our common shares at a price to the public of \$5.00 per share. Of these common shares, 20,000,000 were sold by us and 10,000,000 were sold by certain selling shareholders. Net proceeds to us were approximately \$94.7 million after deducting underwriting discounts and commissions and offering expenses. We did not receive any proceeds from the sale of common shares by the selling shareholders in the offering.

In February 2023, we completed an underwritten public offering of 30,666,665 of our common shares (including 3,999,999 common shares issued and sold upon the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$7.50 per share. Net proceeds to us were approximately \$216.9 million after deducting underwriting discounts and commissions and offering expenses.

In September 2023, we entered into common share purchase and sale agreements with certain institutional investors, pursuant to which we sold an aggregate of 19,600,685 of our common shares at a purchase price of \$10.21 per share. Net proceeds to us were approximately \$199.8 million after deducting offering expenses.

Sumitomo Transaction

In December 2019, we closed the Sumitomo Transaction, including the transfer of our ownership interest in five Vants – Myovant, Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd. – to 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 and (ii) provided Sumitomo and Sumitovant with certain rights over and access to our proprietary technology platforms, DrugOme and Digital Innovation. In exchange for these components of the Sumitomo Transaction, we received approximately \$1.9 billion in cash, which was in addition to the approximately \$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.

In October 2022, Myovant entered into an agreement with Sumitovant, its majority shareholder, under which Sumitovant would acquire the remaining shares of Myovant not already owned by Sumitovant at a price of \$27.00 per share in a cash transaction (the “Myovant Transaction”). The acquisition of Myovant by Sumitovant was completed in March 2023. In connection with the closing of the Myovant Transaction, we received approximately \$114.6 million in March 2023 for the sale of the Myovant Top-Up Shares. Refer to Note 9, “Discontinued Operations” of our audited financial statements for additional information.

Consolidated Vant Equity Financing Transactions

Since inception, we have completed multiple Vant equity financing transactions, including the following:

Immunovant

In December 2019, Immunovant raised \$111.0 million (including \$5.1 million related to common shares purchased by us) through a business combination with Health Sciences Acquisition Corporation, a special purpose acquisition company.

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.

In October 2022, Immunovant completed an underwritten public offering of 12,500,000 shares of its common stock (including 416,667 shares of common stock purchased by us) at a price to the public of \$6.00 per share, for net proceeds to Immunovant of approximately \$70.2 million after deducting underwriting discounts and commissions and offering expenses.

In October 2023, Immunovant completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by us on the same terms as other investors in the offering and the full exercise of the underwriters’ option to purchase 1,105,500 additional shares of common stock) at a price to the public of \$38.00 per share. Concurrent with the public offering, we purchased 4,473,684 shares of Immunovant’s common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of \$38.00 per share. The net proceeds to Immunovant were approximately \$466.7 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses.

Consolidated Vant Debt Financings

Since inception, we have completed multiple Vant debt financings, including the following:

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 (the “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.

Following the approval of VTAMA by the FDA in May 2022, Dermavant received \$160.0 million in June 2022 pursuant to the terms of the RIPSAs entered 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., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSAs, Dermavant is obligated to pay royalties based on a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the U.S., up to a cap of \$344.0 million, in exchange for the \$160.0 million in committed funding to be paid to Dermavant, conditioned on the approval of tapinarof by the FDA, which was achieved in May 2022. Dermavant used the RIPSAs proceeds primarily for the milestone obligations to GSK, which was achieved upon FDA approval, and Welichem Biotech Inc., which was achieved upon the first sale of VTAMA.

On May 24, 2024, Dermavant entered into amendments to (i) the NovaQuest Agreement, (ii) the Credit Facility, and (iii) the RIPSAs. Refer to Note 18, “Subsequent Events” of our audited consolidated financial statements for details regarding the amendments.

Other

Datavant

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

Proteovant

In August 2023, we completed a transaction with SK Biopharmaceuticals Co., Ltd. (“SK Bio”), a subsidiary of SK, Inc., pursuant to which SK Bio purchased all of our shares in Proteovant in exchange for \$47.5 million.

Telavant

In December 2023, we completed the sale of our entire equity interest in our majority-owned subsidiary, Telavant, to Roche. The Roche Transaction was made pursuant to a Stock Purchase Agreement dated October 22, 2023 among us, Telavant, Pfizer Inc. (“Pfizer”), and Roche. Telavant was jointly formed by us and Pfizer in November 2022 to develop and commercialize RVT-3101, an anti-TL1A antibody in development for ulcerative colitis (“UC”) and Crohn’s disease, in the U.S. and Japan. Prior to the Roche Transaction, we held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer owned the remaining 25%, in each case on an as-converted basis.

Pursuant to the Stock Purchase Agreement, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately \$7.1 billion in cash at the closing of the Roche Transaction and a one-time milestone payment of \$150 million in cash payable upon the initiation of a Phase 3 trial in UC. The \$7.1 billion in closing consideration was paid to all of Telavant’s equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction, and this same treatment will be applied to the one-time milestone payment. We received an upfront payment of approximately \$5.2 billion in cash as our pro rata portion of the consideration upon closing of the Roche Transaction. Additionally, we are eligible to receive approximately \$110 million for our pro rata portion of the one-time milestone payment if the milestone payment condition is satisfied.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the discovery efforts, preclinical activities, clinical trials and potential commercialization of our product candidates. Additionally, we expect to incur significant commercialization expenses with respect to VTAMA. 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 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;
- build out our sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize VTAMA and any drug candidates for which we may obtain regulatory approval; and
- operate as a public company.

In the future, we may require significant additional capital to continue our operations, pursue business opportunities or strategic transactions, or respond to challenges, competition or unforeseen circumstances. Until such time, if ever, that we can generate substantial revenues, we may finance future cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations at Roivant and the Vants. To the extent that we raise additional capital by issuing equity securities at Roivant or the Vants, our existing shareholders' ownership, or our ownership in the Vants, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of our shareholders. 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 products and 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 adequate funds are not available to us, we may be required to forego potential in-licensing or acquisition opportunities, delay, limit or terminate one or more development or discovery programs, scale back marketing efforts for our current and future products or be unable to expand operations or otherwise capitalize on business opportunities, which could materially affect our business, prospects, financial condition and results of operations.

Finally, as part of our ongoing business strategy we regularly evaluate new acquisition and in-licensing opportunities as well as our capital structure. We may from time to time use our existing cash to fund such opportunities or to retire outstanding debt obligations or to return capital to shareholders through share repurchases or the issuance of cash dividends on our common shares to optimize our capital structure. See "Risk Factors—Risks Related to Our Business and Industry—We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management" for more information.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended March 31, 2024 and 2023:

	Years Ended March 31,	
	2024	2023
	<i>(in thousands)</i>	
Net cash used in operating activities	\$ (765,268)	\$ (843,393)
Net cash provided by (used in) investing activities	\$ 5,203,623	\$ (44,269)
Net cash provided by financing activities	\$ 419,364	\$ 499,462

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 for non-cash items and changes in working capital.

For the year ended March 31, 2024, cash used in operating activities decreased by \$78.1 million to \$765.3 million compared to the year ended March 31, 2023 due to greater cash requirements to fund operations during the year ended March 31, 2023.

Investing Activities

Cash flow from investing activities includes proceeds from sale of Telavant net assets, milestone payments, cash decreases upon deconsolidation of subsidiaries, proceeds from sale of subsidiary interests and other equity interests, and purchase of property and equipment.

For the year ended March 31, 2024, cash flow from investing activities changed by \$5.2 billion to net cash provided by investing activities of \$5.2 billion from net cash used in investing activities of \$44.3 million for the year ended March 31, 2023. This change in cash flow from investing activities is primarily due to proceeds received upon closing of the Roche Transaction during the year ended March 31, 2024.

Financing Activities

For the year ended March 31, 2024, cash provided by financing activities decreased by \$80.1 million to \$419.4 million compared to the year ended March 31, 2023. During the year ended March 31, 2024, net proceeds were primarily generated by the issuance of common shares of our majority-owned subsidiary Immunovant as well as the issuance of our common shares pursuant to purchase and sale agreements entered with certain institutional investors. During the year ended March 31, 2023, proceeds were generated by funding pursuant to the terms of the RIPSAs following the approval of VTAMA by the FDA in May 2022 as well as net proceeds from the issuance of our common shares and the common shares of our majority-owned subsidiary Immunovant.

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.

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 Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Product Revenue Reserves

We recognize revenue when the customer obtains control of the product, which occurs at a point in time, either upon shipment or delivery to the customer. Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established that result from (a) invoice discounts for prompt payment and specialty distributor and specialty pharmacy service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) performance rebates and administrative fees, (d) product returns and (e) costs of co-pay assistance programs for patients. We establish reserves based on these gross-to-net adjustments, which are based on amounts earned or to be claimed on the related sale and are classified as reductions of accounts receivable (if the amount is payable to the customer) or accrued expenses and other current liabilities (if the amount is payable to a party other than a customer). Where appropriate, we utilize the expected value method to determine the appropriate amount for estimates of variable consideration. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, our historical experience, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we adjust these estimates in the period such change in estimate becomes known, which could affect net product revenue and earnings in the period of the adjustment.

We make significant estimates and judgments that materially affect our recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts may be submitted to us significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. We will adjust our estimates based on new information, including information regarding actual rebates, chargebacks and discounts for our products, as it becomes available.

The following table provides a summary of activity with respect to our sales allowances and accruals (in thousands):

	March 31, 2024	March 31, 2023
Sales return, rebate, and discounts balances, beginning of year	\$ (20,794)	\$ —
Reduction of gross sales	(207,372)	(129,717)
Cash payments	199,151	108,923
Sales return, rebate and discounts balances, end of year	<u>\$ (29,015)</u>	<u>\$ (20,794)</u>

Accrued Research and Development Expenses, Including Clinical Trial Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. We record accruals for estimated costs of research and development activities, including preclinical studies, clinical trials, and contract manufacturing, conducted by third-party service providers. Our process for determining such estimates includes reviewing open contracts, vendor agreements, and purchase orders; communicating with our internal personnel and external service providers to understand the progress or stage of completion of services performed on our behalf; and estimating the associated costs for these services when we have not yet been invoiced. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

We recognize expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract. This may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on various factors, including the successful enrollment of patients and the completion of clinical trial milestones. The majority of our service providers invoice us in arrears based on a pre-determined schedule or when contractual milestones are met. In making these estimates, we consider various factors, including status and timing of services performed, the number of patients enrolled, and the rate of patient enrollment. If the actual timing of the performance of services or the level of effort varies from our estimate, the accrual or prepaid expense is adjusted accordingly.

Other examples of estimated accrued research and development expenses include fees paid to:

- a. investigative sites in connection with clinical trials;
- b. vendors in connection with preclinical and clinical development activities; and
- c. CMOs in connection with the production of product and clinical trial materials.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period.

Valuation of Investment in Datavant

We hold an equity method investment in Datavant, which is a privately-held company. We do not consolidate Datavant as we do not have a controlling financial interest. Our investment in Datavant is subject to the equity method of accounting, and we have elected the fair value option to continuously remeasure the investment to fair value each reporting period with changes in fair value reflected in earnings. We have engaged an independent valuation specialist to determine the fair value as of each reporting date.

The fair value of our investment in Datavant uses significant unobservable inputs and is therefore classified as a Level 3 financial instrument. The estimate of fair value for this investment was determined using the income approach and implementation of the option pricing method (“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.

Recently Adopted Accounting Pronouncements

We did not adopt any material accounting pronouncements during the year ended March 31, 2024.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under SEC rules and regulations, we are not required to provide the information required by this item in this report because we are eligible to use the scaled disclosure requirements applicable to a “smaller reporting company.”

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Roivant Sciences Ltd.

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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, 2024 and 2023, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and redeemable noncontrolling interest and cash flows for each of the two years in the period ended March 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of March 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated May 30, 2024 expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Clinical Trial Accrual

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by contract research organizations. In making these estimates, the Company considers various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment.

Auditing the Company's accrual for clinical trial costs is especially complex due to the fact that information necessary to estimate the accruals is accumulated from clinical research organizations and the Company's assessment of that information is subject to variability and uncertainty. In addition, in certain circumstances, the determination of the nature and amount of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that addressed the identified risks related to the information used in the Company's process for recording clinical trial accruals. For example, we tested controls over management's review of clinical trial progress in comparison to information and invoices received from third parties, and over the completeness and accuracy of data used to calculate the accrual.

To test the clinical trial accrual, our audit procedures included, among others, reading a sample of the Company's agreements with the service providers to understand key financial and contractual terms and testing the accuracy and completeness of the underlying data used in the accrual computations. We also evaluated management's estimates of the vendor's progress for a sample of clinical trials by making direct inquiries of the Company's operations personnel overseeing the clinical trials and obtaining information directly from certain service providers about the service providers' estimate of costs that had been incurred through March 31, 2024. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

Valuation of Investment in Datavant

Description of the Matter

At March 31, 2024, the fair value of the Company's minority equity investment in Heracles Parent, L.L.C. ("Datavant") was \$147.5 million and was classified as Level 3 within the fair value hierarchy. As discussed in Notes 4 and 16 to the consolidated financial statements, the Company has elected the fair value option to account for its investment in Datavant. Management determines the fair value of the Company's investment in Datavant using the income approach and implementation of the option pricing method, which uses significant unobservable inputs. Determining the fair value of the Company's investment in Datavant requires management to make significant judgments about the valuation methodologies, including the unobservable inputs and other assumptions and estimates used in the measurements.

Auditing the fair value of the Company's investment in Datavant was complex and required substantial auditor judgment due to the significant estimation required in determining the fair value of the investment in Datavant. In particular, to value its investment in Datavant, the Company used significant unobservable inputs such as the weighted average cost of capital, revenue growth rate, earnings before interest, taxes, depreciation and amortization and terminal growth rate, which are affected by expectations about future market or economic conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the process for valuing the Company's investment in Datavant, including controls over management's review of the significant inputs described above.

To test the fair value of the Company's investment in Datavant, our audit procedures included, among others, assessing the valuation methodologies used and testing the significant unobservable inputs discussed above, including testing the completeness, accuracy and relevance of underlying data used by the Company in the valuation. We compared the significant inputs and underlying data used by management to current industry and economic trends, historical financial results, and other relevant factors. We analyzed the significant unobservable inputs to evaluate the change in the fair value of the Company's investment in Datavant resulting from changes in the inputs. We also assessed the historical accuracy of the underlying financial projections developed by Datavant by comparing to actual historical results. In addition, we involved our valuation specialists to assist in evaluating the valuation methodology and significant unobservable inputs described above used to develop the fair value estimate. The valuation specialists' procedures included independently developing fair value estimates and comparing them to the amounts recorded.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Iselin, New Jersey

May 30, 2024

ROIVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,535,706	\$ 1,676,813
Other current assets	196,122	121,774
Total current assets	<u>6,731,828</u>	<u>1,798,587</u>
Property and equipment, net	19,058	39,086
Operating lease right-of-use assets	46,892	53,251
Investments measured at fair value	247,753	304,317
Intangible assets, net	137,842	144,881
Other assets	39,109	49,482
Total assets	<u>\$ 7,222,482</u>	<u>\$ 2,389,604</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 53,225	\$ 37,830
Accrued expenses	175,586	167,129
Operating lease liabilities	9,893	11,693
Current portion of long-term debt (includes \$6,000 and \$26,940 accounted for under the fair value option at March 31, 2024 and 2023, respectively)	12,000	40,720
Other current liabilities	16,054	15,076
Total current liabilities	<u>266,758</u>	<u>272,448</u>
Liability instruments measured at fair value	25,737	63,546
Operating lease liabilities, noncurrent	47,265	53,476
Long-term debt, net of current portion (includes \$204,371 and \$180,700 accounted for under the fair value option at March 31, 2024 and 2023, respectively)	430,591	375,515
Other liabilities	3,602	17,032
Total liabilities	<u>773,953</u>	<u>782,017</u>
Commitments and contingencies (Note 14)		
Shareholders' equity:		
Common shares, par value \$0.000000341740141 per share, 7,000,000,000 shares authorized and 806,677,954 and 760,143,393 shares issued and outstanding at March 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	5,396,492	4,933,137
Retained earnings / (accumulated deficit)	576,172	(3,772,754)
Accumulated other comprehensive loss	(4,083)	(2,617)
Shareholders' equity attributable to Roivant Sciences Ltd.	<u>5,968,581</u>	<u>1,157,766</u>
Noncontrolling interests	479,948	449,821
Total shareholders' equity	<u>6,448,529</u>	<u>1,607,587</u>
Total liabilities and shareholders' equity	<u>\$ 7,222,482</u>	<u>\$ 2,389,604</u>

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 amounts)

	Years Ended March 31,	
	2024	2023
Revenues:		
Product revenue, net	\$ 75,057	\$ 28,011
License, milestone and other revenue	49,738	33,269
Revenue, net	<u>124,795</u>	<u>61,280</u>
Operating expenses:		
Cost of revenues	15,560	13,128
Research and development (includes \$34,595 and \$30,914 of share-based compensation expense for the years ended March 31, 2024 and 2023, respectively)	501,736	525,215
Acquired in-process research and development	26,450	97,749
Selling, general and administrative (includes \$164,841 and \$186,603 of share-based compensation expense for the years ended March 31, 2024 and 2023, respectively)	687,443	600,506
Total operating expenses	<u>1,231,189</u>	<u>1,236,598</u>
Gain on sale of Telavant net assets	5,348,410	—
Income (loss) from operations	<u>4,242,016</u>	<u>(1,175,318)</u>
Change in fair value of investments	47,973	20,815
Change in fair value of debt and liability instruments	78,943	78,001
Gain on deconsolidation of subsidiaries	(32,772)	(29,276)
Interest income	(146,425)	(32,184)
Interest expense	34,778	27,968
Other expense (income), net	6,089	(15,808)
Income (loss) from continuing operations before income taxes	4,253,430	(1,224,834)
Income tax expense	22,224	5,190
Income (loss) from continuing operations, net of tax	4,231,206	(1,230,024)
Income from discontinued operations, net of tax	—	114,561
Net income (loss)	<u>4,231,206</u>	<u>(1,115,463)</u>
Net loss attributable to noncontrolling interests	(117,720)	(106,433)
Net income (loss) attributable to Roivant Sciences Ltd.	<u>\$ 4,348,926</u>	<u>\$ (1,009,030)</u>
Amounts attributable to Roivant Sciences Ltd.:		
Income (loss) from continuing operations, net of tax	\$ 4,348,926	\$ (1,123,591)
Income from discontinued operations, net of tax	—	114,561
Net income (loss) attributable to Roivant Sciences Ltd.	<u>\$ 4,348,926</u>	<u>\$ (1,009,030)</u>
Net income (loss) per common share, basic:		
Income (loss) from continuing operations	\$ 5.55	\$ (1.58)
Income from discontinued operations, net of tax	\$ —	\$ 0.16
Net income (loss)	\$ 5.55	\$ (1.42)
Net income (loss) per common share, diluted:		
Income (loss) from continuing operations	\$ 5.23	\$ (1.58)
Income from discontinued operations, net of tax	\$ —	\$ 0.16
Net income (loss)	\$ 5.23	\$ (1.42)
Weighted average shares outstanding:		
Basic	783,248,906	712,791,115
Diluted	831,049,444	712,791,115

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Comprehensive Income (Loss)
(in thousands)

	Years Ended March 31,	
	2024	2023
Net income (loss)	\$ 4,231,206	\$ (1,115,463)
Other comprehensive loss:		
Foreign currency translation adjustment	(936)	(1,490)
Total other comprehensive loss	(936)	(1,490)
Comprehensive income (loss)	4,230,270	(1,116,953)
Comprehensive loss attributable to noncontrolling interests	(117,190)	(106,252)
Comprehensive income (loss) attributable to Roivant Sciences Ltd.	\$ 4,347,460	\$ (1,010,701)

The accompanying notes are an integral part of these consolidated financial statements.

ROIVANT SCIENCES LTD.
Consolidated Statements of Shareholders' Equity and Redeemable Noncontrolling Interest
(in thousands, except share data)

	Shareholders' Equity							
	Redeemable Noncontrolling Interest	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	(Accumulated Deficit) / Retained Earnings	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount					
Balance at March 31, 2022	\$ 22,491	694,975,965	\$ —	\$ 4,421,614	\$ (946)	\$ (2,763,724)	\$ 381,999	\$ 2,038,943
Issuance of the Company's common shares, net of issuance costs	—	50,666,665	—	311,683	—	—	—	311,683
Issuance of common shares in connection with equity incentive plans and tax withholding payments	—	10,903,648	—	(8,737)	—	—	—	(8,737)
Issuance of the Company's common shares related to settlement of transaction consideration	—	1,455,719	—	—	—	—	—	—
Issuance of the Company's common shares and other consideration for an acquisition	—	2,029,877	—	8,836	—	—	112	8,948
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	—	(5,463)	—	—	5,463	—
Issuance of subsidiary common shares, net of issuance costs	—	—	—	19,599	—	—	48,129	67,728
Subsidiary stock options exercised	—	—	—	392	—	—	278	670
Issuance of subsidiary preferred shares	—	—	—	—	—	—	87,500	87,500
Deconsolidation of subsidiaries	(22,491)	—	—	—	—	—	(292)	(292)
Issuance of common shares under employee stock purchase plan	—	111,519	—	316	—	—	—	316
Share-based compensation	—	—	—	184,897	—	—	32,884	217,781
Foreign currency translation adjustment	—	—	—	—	(1,671)	—	181	(1,490)
Net loss	—	—	—	—	—	(1,009,030)	(106,433)	(1,115,463)
Balance at March 31, 2023	<u>\$ —</u>	<u>\$ 760,143,393</u>	<u>\$ —</u>	<u>\$ 4,933,137</u>	<u>\$ (2,617)</u>	<u>\$ (3,772,754)</u>	<u>\$ 449,821</u>	<u>\$ 1,607,587</u>
Issuance of the Company's common shares, net of issuance costs	—	19,600,685	—	199,822	—	—	—	199,822
Issuance of the Company's common shares in connection with equity incentive plans, net of forfeitures, and tax withholding payments	—	18,926,077	—	10,857	—	—	—	10,857
Issuance of the Company's common shares related to settlement of warrants	—	7,554,549	—	83,264	—	—	—	83,264
Issuance of the Company's common shares related to settlement of transaction consideration	—	313,023	—	—	—	—	—	—
Issuance of the Company's common shares under employee stock purchase plan	—	140,227	—	951	—	—	—	951
Issuance of subsidiary common shares, net of issuance costs	—	—	—	129,763	—	—	108,970	238,733
Subsidiary stock options exercised	—	—	—	3,192	—	—	2,550	5,742
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	—	(106,531)	—	—	106,531	—
Deconsolidation of subsidiaries	—	—	—	—	—	—	(35,148)	(35,148)
Dividend declared by subsidiary	—	—	—	—	—	—	(6,000)	(6,000)
Disposition of Telavant	—	—	—	—	—	—	(87,500)	(87,500)
Share-based compensation	—	—	—	142,037	—	—	57,914	199,951
Foreign currency translation adjustment	—	—	—	—	(1,466)	—	530	(936)
Net income (loss)	—	—	—	—	—	4,348,926	(117,720)	4,231,206
Balance at March 31, 2024	<u>\$ —</u>	<u>\$ 806,677,954</u>	<u>\$ —</u>	<u>\$ 5,396,492</u>	<u>\$ (4,083)</u>	<u>\$ 576,172</u>	<u>\$ 479,948</u>	<u>\$ 6,448,529</u>

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,	
	2024	2023
Cash flows from operating activities:		
Net income (loss)	\$ 4,231,206	\$ (1,115,463)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash acquired in-process research and development	—	87,749
Share-based compensation	199,627	217,781
Change in fair value of investments	47,973	20,815
Change in fair value of debt and liability instruments	78,943	78,001
Gain on deconsolidation of subsidiaries	(32,772)	(29,276)
Gain on sale of Telavant net assets	(5,348,410)	—
Gain on recovery of contingent consideration	—	(114,561)
Depreciation and amortization	22,036	18,857
Non-cash lease expense	6,845	7,565
Other	10,249	(21,206)
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Other current assets	(81,478)	(31,670)
Other assets	16,488	(17,416)
Accounts payable	22,684	4,359
Accrued expenses	40,150	38,956
Operating lease liabilities	(8,326)	(8,604)
Accrued interest	21,977	18,571
Other liabilities	7,540	2,149
Net cash used in operating activities	<u>(765,268)</u>	<u>(843,393)</u>
Cash flows from investing activities:		
Proceeds from sale of Telavant net assets, net	5,233,396	—
Proceeds from sale of subsidiary interests	47,500	—
Cash decrease upon deconsolidation of subsidiaries	(84,483)	(6,706)
Proceeds from sale of Myovant Top-Up Shares	—	114,561
Milestone payments	—	(140,136)
Purchase of property and equipment	(1,382)	(12,690)
Other	8,592	702
Net cash provided by (used in) investing activities	<u>5,203,623</u>	<u>(44,269)</u>
Cash flows from financing activities:		
Proceeds from issuance of the Company's common shares, net of issuance costs paid	199,822	311,981
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	238,733	67,727
Proceeds from subsidiary debt financings, net of financing costs paid	—	159,899
Payment of subsidiary dividend	(6,000)	—
Repayment of debt by subsidiary	(29,158)	(29,452)
Payment of offering costs and loan origination costs	—	(2,250)
Taxes paid related to net settlement of equity awards	(37,715)	(10,881)
Proceeds from exercise of the Company's and subsidiary stock options	54,314	2,814
Payments on principal portion of finance lease obligations	(1,547)	(692)
Proceeds from issuance of the Company's common stock under employee stock purchase plan	951	316
Proceeds from exercise of the Company's warrants	5	—
Payment for redemptions of the Company's warrants	(41)	—
Net cash provided by financing activities	<u>419,364</u>	<u>499,462</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	616	6,281
Net change in cash, cash equivalents and restricted cash	<u>4,858,335</u>	<u>(381,919)</u>
Cash, cash equivalents and restricted cash at beginning of period	<u>1,692,115</u>	<u>2,074,034</u>
Cash, cash equivalents and restricted cash at end of period	<u>\$ 6,550,450</u>	<u>\$ 1,692,115</u>
Non-cash investing and financing activities:		
Cashless exercise of the Company's warrants	\$ 83,258	\$ —
Issuance of the Company's common shares and other consideration for an acquisition	\$ —	\$ 9,694
Other	\$ 2,231	\$ 10,860
Supplemental disclosure of cash paid:		
Income taxes paid	\$ 12,354	\$ 5,128
Interest paid	\$ 10,268	\$ 5,303

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 the lives of patients by accelerating the development and commercialization of medicines that matter. The Company does this by creating nimble subsidiaries or “Vants” to develop and commercialize its medicines and technologies. Beyond therapeutics, the Company also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. The Company was founded on April 7, 2014 as a Bermuda exempted limited company.

VTAMA® (tapinarof) was approved by the United States Food and Drug Administration (“FDA”) in May 2022 for the treatment of plaque psoriasis in adult patients. A Supplemental New Drug Application for VTAMA (tapinarof) for the topical treatment of atopic dermatitis in adults and children 2 years of age and older was accepted by the FDA in April 2024.

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, “Equity Method Investments” for further discussion of the Company’s investments in unconsolidated entities.

RSL completed its business combination (the “Business Combination”) with Montes Archimedes Acquisition Corp. (“MAAC”), a special purpose acquisition company, on September 30, 2021 and on October 1, 2021 began trading on Nasdaq under the ticker symbol “ROIV.”

(B) Liquidity

Historically, the Company incurred significant operating losses and negative cash flows from operations since its inception. During the year ended March 31, 2024, the Company recognized a gain of approximately \$5.3 billion on the sale of Telavant Holdings, Inc. (“Telavant”) net assets. As of March 31, 2024, the Company had cash and cash equivalents of approximately \$6.5 billion and its retained earnings was approximately \$576.2 million. For the years ended March 31, 2024 and 2023, the Company had income from continuing operations of approximately \$4.2 billion and incurred a loss from continuing operations of approximately \$1.2 billion, 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. Through its subsidiary, Dermavant Sciences Ltd. (“Dermavant”), the Company has launched its first commercial product, VTAMA, following approval by the FDA in May 2022.

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 to market its product candidates, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and may require additional capital to fully implement its business plan.

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.

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. Certain prior year amounts have been reclassified to conform with the current period presentation. These reclassifications had no effect on the previously reported results of operations. 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 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 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.

(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.

(C) Concentrations

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.

The Company has long-lived assets in different geographic locations. As of March 31, 2024 and 2023, a majority of the Company's long-lived assets were located in the United States ("U.S.").

(D) 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.

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, 2024	March 31, 2023
Cash and cash equivalents	\$ 6,535,706	\$ 1,676,813
Restricted cash (included in "Other current assets")	5,367	5,011
Restricted cash (included in "Other assets")	9,377	10,291
Cash, cash equivalents and restricted cash	<u>\$ 6,550,450</u>	<u>\$ 1,692,115</u>

(E) 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 contingent loss, including an estimable range, if possible.

(F) Inventory

Inventories are recorded at the lower-of-cost or net realizable value, with cost determined based on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of the Company's business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventories is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. Inventories include the cost for raw materials, the cost to manufacture the raw materials into finished goods, freight charges, and overhead.

The Company performs an assessment of the recoverability of inventories during each reporting period and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such impairment charges are recorded as a component of cost of revenues in the consolidated statements of operations.

Prior to initial regulatory approval, the Company expenses costs relating to the production of inventory as research and development expenses when incurred. After such time as the product receives initial regulatory approval, the Company capitalizes inventory costs related to the product.

Inventory is included in "Other current assets" on the accompanying consolidated balance sheets.

(G) Property and Equipment

Property and equipment, consisting primarily of computers, laboratory and other 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
Laboratory and other equipment	5 - 10 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.

(H) Investments

Investments in equity securities may 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, "Equity Method Investments."

(I) Intangible Assets, Net

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. The Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 5, "Intangible Assets."

(J) Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by U.S. GAAP 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"); Class A units of Heracles Parent, L.L.C. ("Datavant"); liability instruments issued, including the warrants (prior to their settlement) and earn-out shares liabilities issued in connection with the Company's business combination with MAAC (as discussed in Note 15, "Earn-Out Shares, Public Warrants and Private Placement Warrants"); its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus 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 Class A units of Datavant, and liability instruments issued, excluding the Public Warrants (as defined and discussed in Note 15, "Earn-Out Shares, Public Warrants and Private Placement Warrants"), are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. Prior to their settlement, the Public Warrants were publicly traded and therefore were classified as Level 1 as the Public Warrants had a readily determinable fair value. Cash and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. 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, 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.

(K) Research and Development Expenses

Research and development (“R&D”) costs are expensed as incurred. R&D expenses primarily consist of costs associated with preclinical studies and clinical trials as well as employee-related expenses, such as salaries, share-based compensation, and benefits, for employees engaged in R&D activities. The Company records accruals for estimated costs of R&D activities, including preclinical studies, clinical trials, and contract manufacturing, conducted by third-party service providers. The Company determines the estimates by reviewing open contracts, vendor agreements, and purchase orders; communicating with internal personnel and external service providers to understand the progress or stage of completion of services performed on its behalf; and estimating the associated costs for these services that have not yet been invoiced. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual or prepaid expense is adjusted accordingly.

(L) Acquired In-Process Research and Development Expenses

Acquired in-process research and development (“IPR&D”) expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

The Company evaluates in-licensed agreements 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 in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and have no alternative future use, the Company expenses payments made under such license agreements as acquired in-process research and development expense in its consolidated statements of operations. In those cases, payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones are capitalized and amortized to cost of revenue.

(M) Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, sales incentive compensation, and benefits, for employees engaged in SG&A activities. SG&A employees include those responsible for the identification and acquisition or in-license of new drug candidates as well as for managing Vant operations and facilitating the use of the Company’s platform and technologies at the Vants. SG&A expenses also consist of marketing programs, advertising, legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations. Additionally, SG&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.

(N) Leases

The Company determines if an arrangement includes a lease at the inception of the agreement. Leases are classified at lease commencement as either operating leases or finance leases. Operating leases are included in “Operating lease right-of-use assets”, “Operating lease liabilities”, and “Operating lease liabilities, noncurrent” on the accompanying consolidated balance sheets. Commitments under finance leases are not significant and are included in “Property and equipment, net”, “Other current liabilities”, and “Other liabilities” on the accompanying consolidated balance sheets. For each of the Company’s lease arrangements, the Company records a right-of-use asset representing the Company’s right to use an underlying asset for the lease term and a lease liability representing the Company’s obligation to make lease payments. Lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the expected lease term. If the interest rate implicit in the Company’s leases is not readily determinable, in determining the weighted-average discount rate used to calculate the net present value of lease payments, the Company utilizes an estimate of its incremental borrowing rate. 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. Lease expense for the Company’s leases is recognized on a straight-line basis over the lease term and variable lease costs are expensed as incurred.

The Company elected the practical expedient not to apply the recognition and measurement requirements to short-term leases, which is any lease with a term of one year or less as of the lease commencement date. Leases may require the Company to pay additional amounts for taxes, insurance, maintenance, and other expenses, which are generally referred to as non-lease components. The Company has elected the practical expedient to combine lease and non-lease components. If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of economic factors present as of the lease commencement date.

(O) 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. The Company's policy is to recognize interest and/or penalties related to income tax matters in provision for income taxes.

(P) 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. When determining the grant-date fair value of stock-based awards, management further considers whether an adjustment is required to the observable market price or volatility of the Company's common stock that is used in the valuation as a result of material non-public information, if that information is expected to result in a material increase in share price.

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 shares of common stock. Since the Company has limited 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.

One of the inputs to the Black-Scholes option pricing model is the fair value of the Company's common shares. Prior to the closing of its business combination with MAAC, as a privately held company, the Company estimated the fair value of the shares of common stock underlying its share-based awards on each grant date. 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 exercised reasonable judgment and considered 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 considered 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.

The Company applies a similar methodology to estimate the fair value of the shares of common stock underlying share-based awards issued by its privately held Vants. Following the closing of the Company's business combination with MAAC, RSL's common shares became publicly traded and the Company began determining the fair value of each common share underlying share-based awards based on the closing price of its common shares as reported by Nasdaq on the date of grant. Therefore, it will not be necessary to determine the fair value of the new stock-based award pursuant to the methodology described above.

(Q) 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 (income), net" in the Company's statements of operations.

(R) 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.

Product Revenue, Net

The Company began recognizing product revenues after the initial product launch of VTAMA following approval by the FDA in May 2022.

The Company sells VTAMA in the U.S. principally through wholesale, specialty distribution and pharmacy channels (collectively, "customers"). These customers subsequently resell the product to healthcare providers and patients. In addition to distribution agreements with customers, the Company enters into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's product. Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, either upon shipment or delivery to the customer.

Revenues from product sales are recorded at the net sales price, or "transaction price," which includes estimates of variable consideration for which reserves are established that result from: (a) invoice discounts for prompt payment, cash payment and distribution service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) performance rebates and administrative fees, (d) product returns and (e) costs of co-pay assistance programs for patients. These reserves are based on amounts earned or to be claimed on the related sale and are classified as reductions of accounts receivable (if the amount is payable to the customer) or accrued expenses and other current liabilities (if the amount is payable to a party other than a customer). Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, the Company's historical experience, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts these estimates in the period such change in estimate becomes known, which could affect net product revenue and earnings in the period of the adjustment.

More specifically, these adjustments include the following:

- a Prompt Pay and Cash Pay Discounts: The Company generally provides invoice discounts on product sales to its customers for prompt payment and/or cash payment. The Company estimates the amount of such discounts that will be utilized and deducts the amount from its gross product revenues and accounts receivable at the time such revenues are recognized.
- b Customer Fees: The Company pays fees to its customers for account management, data management, and other administrative services. To the extent the services received are distinct from sales of products to the customer, the Company records these payments in selling, general and administrative expenses.

- c Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a wholesaler or specialty distributor. Contracted customers, which currently consist primarily of public health service institutions, federal government entities, pharmaceutical benefit managers, and health maintenance organizations, generally purchase the product at a discounted price. The wholesaler or specialty distributor, in turn, charges back to the Company the difference between the price initially paid by the wholesaler or specialty distributor and the discounted price paid to the wholesaler or specialty distributor by the contracted customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales to contracted customers.
- d Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit as well as contracted discounts with pharmaceutical benefit managers and health maintenance organizations. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with payers or statutory requirements pertaining to Medicaid and Medicare benefit providers. The allowance for rebates is based on contractual or statutory discount rates, estimated payer mix, and expected utilization. The Company's estimates for expected utilization of rebates are based on historical data received from wholesalers, specialty distributors, and pharmacies since launch, as well as analog data from similar products. The Company monitors sales trends and adjusts the allowance on a regular basis to reflect the most recent rebate experience. The Company's liability for these rebates consists of invoices received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.
- e Co-payment Assistance: The Company offers co-payment assistance to patients. Co-payment assistance is accrued based on an estimate of the number of co-payment assistance claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.
- f Product Returns: Consistent with industry practice, the Company offers its customers limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution or customer agreement. The Company does not allow product returns for product that has been dispensed to a patient. In arriving at its estimate for product returns, the Company considers historical product returns, the underlying product demand, and industry specific data.

License, Milestone and Other Revenue

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 contracts from subscription and service-based fees recognized for the use of certain technology internally developed. Subscription revenue is recognized ratably over the contract period.

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, 2024 and 2023. Trade receivables, net is included in "Other current assets" on the accompanying consolidated balance sheets.

(S) Cost of Revenues

Following the initial product launch of VTAMA, the Company began to recognize cost of product revenues, which includes the cost of producing and distributing inventories related to product revenue during the respective period, including manufacturing, freight, and indirect overhead costs. Additionally, cost of product revenues may include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. Cost of product revenues for the years ended March 31, 2024 and 2023 is included in "Cost of revenues" on the accompanying consolidated statements of operations.

Cost of revenues related to the Company's subscription and service-based revenue recognized for the use of technology developed consists primarily of employee, hosting, and third-party data costs.

(T) Recently Adopted Accounting Pronouncements

The Company did not adopt any material accounting pronouncements during the year ended March 31, 2024.

(U) Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2025, and subsequent interim periods, with early adoption permitted. These amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which includes updates to the income tax disclosures related to the rate reconciliation and disaggregation of income taxes paid by jurisdiction. The amendments are effective for fiscal years beginning after December 15, 2024 and is applicable to the Company's fiscal year beginning April 1, 2025, with early adoption permitted. The amendments should be applied prospectively, however retrospective application is permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements.

Note 3—Revenue

(A) Product Revenue, Net

The Company's product revenue, net relates entirely to the sale of VTAMA in the U.S. The Company began generating product revenue, net from sales of VTAMA in the U.S. following the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022. The Company records product revenue net of estimated chargebacks, discounts, rebates, returns, and other allowances associated with the respective sales.

(B) License, Milestone and Other Revenue

Covant

In March 2023, Covant Therapeutics Operating, Inc. ("Covant"), a wholly-owned subsidiary of the Company, entered into a collaboration and license agreement with Boehringer Ingelheim International, GmbH ("BI"). Under the terms of the collaboration and license agreement, Covant will conduct discovery work on RNA-specific adenosine deaminase 1 ("ADAR1") targeting and modulating compounds and BI will receive an exclusive, royalty-bearing, worldwide transferable, sublicensable license to exploit Covant's ADAR1 binding compounds and/or resulting products worldwide. In exchange, Covant received a nonrefundable, upfront payment of \$10.0 million and will be eligible to receive up to an additional \$471.0 million in contingent milestone payments including specified research, development, regulatory, and commercialization milestones; and tiered royalties on global sales.

Dermavant

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. The Company evaluated the collaboration and license agreement and concluded that JT is a customer. During the year ended March 31, 2024, a development milestone was achieved, and the Company received a payment of \$15.0 million. Accordingly, the Company recorded \$15.0 million as license, milestone and other revenue in the accompanying consolidated statements of operations for the year ended March 31, 2024.

Genevant

Genevant Sciences Ltd. ("Genevant"), a technology-focused nucleic acid delivery and development company, is party to various collaboration and license agreements. Related to these agreements, the Company recorded \$24.9 million and \$15.1 million as license, milestone, and other revenue in the accompanying consolidated statements of operations for the years ended March 31, 2024 and 2023, respectively.

Note 4—Equity Method Investments

The Company maintains equity method investments in certain entities. As of March 31, 2024 and 2023, the most significant of these were the Company's investments in Arbutus and Datavant, which are accounted for using the fair value option.

The Company determined that it does not control these entities and as a result does not consolidate these entities. Due to the Company's significant influence over operating and financial policies of these entities, the entities are considered related parties of the Company.

The Company holds an investment in Arbutus in the form of 38,847,462 common shares of Arbutus.

The Company additionally holds an investment in Class A units of Datavant. The fair value of the Company's investment in Datavant 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 16, "Fair Value Measurements" for more information.

Summarized Equity Method Investment Details

Details regarding significant equity method investments are as follows:

	Ownership %		Aggregate Fair Value (in millions)	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Datavant ⁽¹⁾	9%	17%	\$ 147.5	\$ 178.6
Arbutus	22%	24%	\$ 100.2	\$ 117.7

(1) The ownership percentage represents the Company's equity interest in the outstanding Class A units in Datavant. Datavant'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. Refer above for additional information regarding investment.

The Company recognized unrealized losses (gains) on its significant equity method investments in the accompanying consolidated statements of operations as follows:

	Unrealized Loss (Gain) on Investment (in millions)			
	Years Ended March 31,			
	2024		2023	
Datavant	\$	31.1	\$	15.4
Arbutus	\$	17.5	\$	(1.9)

Summarized consolidated financial information of Datavant, reported on a one quarter lag, is as follows (in thousands):

	Twelve Months Ended December 31,	
	2023	2022
Revenue	\$ 991,107	\$ 873,435
Gross profit	\$ 376,593	\$ 354,561
Net loss	\$ (395,195)	\$ (190,243)

Summarized consolidated financial information of Arbutus is as follows (in thousands):

	Twelve Months Ended March 31,	
	2024	2023
Revenue	\$ 12,986	\$ 33,125
Loss from operations	\$ (80,053)	\$ (71,895)
Net loss	\$ (74,385)	\$ (70,030)

Note 5—Intangible Assets

In July 2018, Dermavant acquired the worldwide rights (other than for China) with respect to certain intellectual property rights retained by Welichem Biotech Inc. ("Welichem") to VTAMA and related compounds from Glaxo Group Limited and GlaxoSmithKline Intellectual Property Development Ltd. (collectively, "GSK") pursuant to an asset purchase agreement. GSK previously acquired rights to a predecessor formulation from Welichem pursuant to an asset purchase agreement between GSK and Welichem entered into in May 2012. The Company evaluated the agreement and determined that the acquired assets did not meet the definition of a business and thus the transaction was accounted for as an asset acquisition.

Following the FDA approval of VTAMA in May 2022, the Company became obligated to pay a regulatory milestone to GSK of £100.0 million (approximately \$126 million on the date of achievement) following the receipt of marketing approval of VTAMA in the U.S. The milestone was paid in July 2022.

Additionally, the first sale of VTAMA in May 2022 resulted in the achievement of a milestone to Welichem Biotech Inc. of CAD\$25.0 million (approximately \$20 million on the date of achievement). The milestone was paid in August 2022.

Both of the above milestones were capitalized as intangible assets upon achievement and are being amortized over their estimated useful lives.

The following table summarizes the Company's recognized intangible assets (in thousands):

	March 31, 2024	March 31, 2023
Gross amount	\$ 155,171	\$ 152,629
Less: accumulated amortization	(17,329)	(7,748)
Net book value	<u>\$ 137,842</u>	<u>\$ 144,881</u>

Amortization expense was \$9.6 million and \$7.5 million for the years ended March 31, 2024 and 2023, respectively. Amortization expense was recorded as part of "Cost of revenues" in the accompanying consolidated statement of operations. Future amortization expense is approximately \$9.5 million for each of the years ending from March 31, 2025 through March 31, 2029 and \$90.3 million thereafter. The Company's intangible assets are denominated in currencies other than U.S. dollar and therefore are subject to foreign currency movements.

Note 6—Recent Transactions

(A) Telavant Disposition

On December 14, 2023 (the "Transaction Date"), the Company completed the sale of its entire equity interest in its majority-owned subsidiary Telavant to Roche Holdings, Inc. ("Roche") (the "Roche Transaction"). The Roche Transaction was made pursuant to a Stock Purchase Agreement dated October 22, 2023 among the Company, Telavant, Pfizer Inc. ("Pfizer"), and Roche (the "Stock Purchase Agreement"). Telavant was jointly formed by the Company and Pfizer in November 2022 to develop and commercialize RVT-3101, an anti-TL1A antibody in development for ulcerative colitis ("UC") and Crohn's disease, in the U.S. and Japan. Telavant's in-license of RVT-3101 from Pfizer 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 \$87.7 million, primarily consisting of preferred stock issued to Pfizer. The acquired rights were determined to have no alternative future use. Accordingly, the Company recorded \$87.7 million as acquired in process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2023. Prior to the Roche Transaction, the Company held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer owned the remaining 25%, in each case on an as-converted basis.

Pursuant to the Stock Purchase Agreement, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately \$7.1 billion in cash at the closing of the Roche Transaction and a one-time milestone payment of \$150 million in cash payable upon the initiation of a Phase 3 trial in UC. The \$7.1 billion in closing consideration was paid to all of Telavant's equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction, and this same treatment will be applied to the one-time milestone payment. The Company received an upfront payment of approximately \$5.2 billion in cash as its pro rata portion of the consideration upon closing of the Roche Transaction. Additionally, the Company is eligible to receive approximately \$110 million for its pro rata portion of the one-time milestone payment if the milestone payment condition is satisfied.

At the closing of the Roche Transaction, Roche acquired the full rights to further develop and manufacture RVT- 3101 and commercialize it in the U.S. and Japan. Outside of the U.S. and Japan, Pfizer holds commercialization rights. In addition, following the closing of the Roche Transaction, Roche acquired Telavant's option to enter into a global collaboration with Pfizer on a next generation p40/TL1A directed bispecific antibody, currently in Phase 1.

The Telavant entity that was sold did not meet the definition of a business, and therefore the Company concluded that the Roche Transaction was a sale of non-financial assets, with control transferred at closing. The sale of Telavant did not meet the criteria for reporting discontinued operations as the sale does not represent a strategic shift in the Company's business. The Company recognized a gain on sale of Telavant net assets of approximately \$5.3 billion during the year ended March 31, 2024 in the accompanying consolidated statements of operations. The gain does not include the Company's portion of the one-time milestone payment, which will be recognized in the period it is achieved. The gain on sale of Telavant net assets qualifies under the substantial shareholding exemption in the United Kingdom ("U.K.") and consequently is not subject to the corporation income tax. The table below summarizes the calculation of the gain.

	<u>(in thousands)</u>
Consideration:	
Upfront cash payment	\$ 5,234,373
Carrying amount of noncontrolling interest derecognized	87,500
Total consideration	5,321,873
Assets sold	
	3,253
Liabilities transferred	29,790
Net liabilities sold	(26,537)
Gain on sale of Telavant net assets	\$ 5,348,410

The pretax loss generated by Telavant was \$71.1 million for the period from April 1, 2023 to the Transaction Date and \$101.9 million for the period from inception on November 14, 2022 to March 31, 2023. The entirety of the Telavant pretax losses was attributable to the Company.

(B) Asset Acquisition

In July 2023, a newly-formed subsidiary in-licensed certain intellectual property rights in exchange for a \$14.0 million upfront cash payment. The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The acquired rights represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded \$14.0 million as acquired in-process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2024.

Additionally, the newly-formed subsidiary agreed to pay up to \$280 million of future development, regulatory, and commercial milestone payments and tiered high-single digit sales-based royalties.

(C) Deconsolidation of Subsidiaries

In July 2023, VantAI Holdings, Inc. ("VantAI"), a wholly-owned subsidiary of the Company, completed a transaction pursuant to which SK, Inc. ("SK") contributed \$6.0 million to VantAI in exchange for preferred shares in VantAI (the "VantAI Preferred Financing"). In August 2023, the Company and SK Biopharmaceuticals Co., Ltd. ("SK Bio"), a subsidiary of SK, completed a transaction pursuant to which SK Bio purchased all of the Company's shares in Proteovant Sciences, Inc. ("Proteovant") in exchange for \$47.5 million.

As a result of changes in governance and voting rights, the Company determined that it no longer held a controlling financial interest in VantAI. Accordingly, the Company deconsolidated VantAI as of July 2023. The Company recorded a \$17.4 million gain on deconsolidation of Proteovant and VantAI in the accompanying consolidated statements of operations for the year ended March 31, 2024.

Upon deconsolidation, the Company recorded its \$9.0 million retained investment in VantAI based upon the fair value of the preferred shares held by the Company. Due to the Company's significant influence over the operating and financial policies of VantAI, the Company will account for its retained interest under the equity method of accounting.

Note 7—Certain Balance Sheet Components

(A) Other Current Assets

Other current assets at March 31, 2024 and 2023 consisted of the following (in thousands):

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Prepaid expenses	\$ 55,096	\$ 60,827
Trade receivables, net	53,545	30,379
Restricted cash	5,367	5,011
Inventory	35,251	2,761
Income tax receivable	1,827	2,356
Interest receivable	27,441	4,909
Other	17,595	15,531
Total other current assets	<u>\$ 196,122</u>	<u>\$ 121,774</u>

(B) Accrued Expenses

Accrued expenses at March 31, 2024 and 2023 consisted of the following (in thousands):

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Research and development expenses	\$ 40,313	\$ 76,278
Compensation-related expenses	61,242	55,186
Sales allowances	23,277	17,569
Other expenses	50,754	18,096
Total accrued expenses	<u>\$ 175,586</u>	<u>\$ 167,129</u>

(C) Other Current Liabilities

Other current liabilities at March 31, 2024 and 2023 consisted of the following (in thousands):

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Deferred revenue	\$ 4,168	\$ 12,444
Income tax payable	10,469	542
Other	1,417	2,090
Total other current liabilities	<u>\$ 16,054</u>	<u>\$ 15,076</u>

Note 8—Long-Term Debt**Dermavant****Funding Agreement with NovaQuest**

In connection with Dermavant's acquisition of tapinarof from 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 the \$117.5 million in total funding from NovaQuest, Dermavant agreed to make fixed payments to NovaQuest under the NovaQuest Agreement upon regulatory approval of tapinarof. For each of the atopic dermatitis and psoriasis indications, Dermavant is required to make quarterly payments to NovaQuest totaling \$176.3 million per indication over a six-year period following regulatory approval of tapinarof for the applicable indication in the U.S. In the event that Dermavant receives regulatory approval for one indication, and Dermavant terminates the development of the other indication for any reason other than a Technical Failure (as defined below), then Dermavant will be required to make the above-referenced quarterly payments to NovaQuest up to \$440.6 million over a 15-year period for the approved indication, which are referred to as 15-year Payments. A Technical Failure is deemed to occur for an indication if the development program for such indication is terminated due to (1) significant safety concerns, (2) material adverse developments or (3) the receipt by Dermavant of a complete response letter or a final non-approval letter from the FDA is expected to result in significant delay or cost to reach commercialization for the applicable indication. In addition, Dermavant is required to make up to \$141.0 million in payments to NovaQuest upon achievement of certain commercial milestones. In the event that Dermavant is required to start making 15-year Payments, then Dermavant has the right to offset such amounts by up to \$88.1 million of the commercial milestone payments, with such offset being applied to the quarterly payments in reverse chronological order (such that the final quarterly payments owed will be used first to offset the commercial milestone payments). The NovaQuest Agreement does not contain any royalty payment requirements on commercialization of tapinarof. Upon receiving FDA approval for the psoriasis indication, Dermavant made its first quarterly payment of \$7.3 million under the NovaQuest Agreement in May 2022 and has made cumulative quarterly payments totaling \$58.8 million as of March 31, 2024.

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 records the changes in the fair value within the consolidated 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, 2024 and 2023, the fair value of the debt was \$210.4 million and \$207.6 million, respectively. Refer to Note 16, "Fair Value Measurements" for additional details regarding the fair value measurement.

The NovaQuest Agreement, Credit Facility (as defined below), and RIPSAs (as defined below) were amended in May 2024. Refer to Note 18, "Subsequent Events" for details regarding the amendments. The below table was adjusted to reflect the amendment to the NovaQuest Agreement.

The carrying balance of the debt issued to NovaQuest was as follows (in thousands):

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Fair value of long-term debt	\$ 210,371	\$ 207,640
Less: current portion	(6,000)	(26,940)
Total long-term debt, net	<u>\$ 204,371</u>	<u>\$ 180,700</u>

Credit Facility with XYQ Luxco

In May 2021, Dermavant and certain of its subsidiaries entered into a \$40.0 million senior secured credit facility (the "Credit Facility") 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 March 31, 2024. 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.

Outstanding debt obligations to XYQ Luxco were as follows (in thousands):

	<u>March 31, 2024</u>	<u>March 31, 2023</u>
Principal amount	\$ 40,000	\$ 40,000
Exit fee	5,000	5,000
Less: unamortized discount and debt issuance costs	(7,514)	(10,170)
Total debt, net	37,486	34,830
Less: current portion	—	—
Total long-term debt, net	<u>\$ 37,486</u>	<u>\$ 34,830</u>

The NovaQuest Agreement, Credit Facility, and RIPSAs (as defined below) were amended in May 2024. Refer to Note 18, "Subsequent Events" for details regarding the amendments. The below table was adjusted to reflect the amendment to the Credit Facility.

Annual maturities, including the exit fee, of outstanding debt obligations to XYQ Luxco as of March 31, 2024 are as follows (in thousands):

<u>Years Ending March 31,</u>	
2025	\$ —
2026	—
2027	—
2028	—
2029	45,000
Thereafter	—
Total	<u>\$ 45,000</u>

Revenue Interest Purchase and Sale Agreement

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., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, Dermavant is obligated to pay royalties based on a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the U.S., up to a cap of \$344.0 million, in exchange for the \$160.0 million in committed funding, which was paid to Dermavant in June 2022 following the approval of tapinarof by the FDA.

The transaction is accounted for as debt. Over the term of the arrangement, the effective interest rate will be updated prospectively each reporting period based on the carrying amount of the note, payments made to date, and the estimated remaining cash flows related to the note.

The NovaQuest Agreement, Credit Facility, and RIPSA were amended in May 2024. Refer to Note 18, “Subsequent Events” for details regarding the amendments. The below table was adjusted to reflect the amendment to the RIPSA.

The RIPSA carrying balance was as follows (in thousands):

	March 31, 2024	March 31, 2023
Carrying balance	\$ 198,810	\$ 178,571
Less: unamortized issuance costs	(4,076)	(4,806)
Total debt, net	194,734	173,765
Less: current portion	(6,000)	(13,780)
Total long-term debt, net	\$ 188,734	\$ 159,985

Note 9—Discontinued Operations

In March 2023, Sumitovant Biopharma Ltd. (“Sumitovant”), a wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. (“Sumitomo”), completed its acquisition of Myovant Sciences Ltd. (“Myovant”), pursuant to an agreement by which Sumitovant acquired all outstanding shares of Myovant not already owned by Sumitovant for \$27.00 per share in cash (the “Myovant Transaction”). Shortly prior to the closing of the Myovant Transaction, RSL received 4,243,005 common shares of Myovant (the “Myovant Top-Up Shares”) from Sumitovant. RSL was entitled to the Myovant Top-Up Shares pursuant to the December 2019 transaction with Sumitomo (the “Sumitomo Transaction”) that included, among other things, the transfer of RSL’s ownership interest in five Vants—Myovant, Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd.—to Sumitovant. The Sumitomo Transaction was presented as discontinued operations during the year ending March 31, 2020, and the right to receive the Myovant Top-Up Shares was treated as a contingent consideration upon a sale of the business and accounted for as a gain contingency.

As part of the Myovant Transaction, the Myovant Top-Up Shares were subsequently acquired back by Sumitovant for \$27.00 per share. The total amount received of \$114.6 million was recorded as gain on sale of common shares of Myovant and presented as “Income from discontinued operations, net of tax” in the accompanying consolidated statements of operations for the year ended March 31, 2023.

In the accompanying consolidated statements of cash flows, the cash flows from discontinued operations are not separately classified. The cash flow item from discontinued operations was as follows (in thousands):

	Year Ended March 31, 2023
Gain on recovery of contingent consideration	\$ (114,561)
Proceeds from sale of Myovant Top-Up Shares	\$ 114,561

Note 10—Shareholders’ Equity

(A) At-the-Market Equity Offering Program

On September 19, 2022, the Company entered into a sales agreement with Cowen and Company, LLC (“Cowen”) to sell its common shares having an aggregate offering price of up to \$400.0 million from time to time through an “at-the-market” equity offering program under which Cowen acts as the Company’s agent (the “ATM Facility”).

As of March 31, 2024, the Company had \$400.0 million of remaining capacity available under the ATM Facility.

(B) Underwritten Public Offerings of Common Shares

In November 2022, the Company completed an underwritten primary and secondary public offering of 30,000,000 common shares of RSL at a price to the public of \$5.00 per share. Of these common shares, 20,000,000 were sold by RSL and 10,000,000 were sold by certain selling shareholders. Net proceeds to the Company were approximately \$94.7 million after deducting underwriting discounts and commissions and offering expenses. The Company did not receive any proceeds from the sale of common shares by the selling shareholders in the offering.

In February 2023, the Company completed an underwritten public offering of 30,666,665 common shares of RSL (including 3,999,999 common shares issued and sold upon the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$7.50 per share. Net proceeds to the Company were approximately \$216.9 million after deducting underwriting discounts and commissions and offering expenses.

(C) Common Share Purchase and Share Agreements

In September 2023, the Company entered into common share purchase and sale agreements with certain institutional investors, pursuant to which the Company sold an aggregate of 19,600,685 of its common shares at a purchase price of \$10.21 per share. Net proceeds to the Company were approximately \$199.8 million after deducting offering expenses.

(D) Disposal of Cytovant

In July 2022, the Company exited its operations in Cytovant Sciences HK Limited ("Cytovant") by transferring all of its equity interest to certain investors holding Series A-1 preference shares of Cytovant in exchange for nominal consideration. As a result of this transaction, the Company deconsolidated Cytovant and recorded a gain on deconsolidation of \$16.8 million, primarily as a result of relieving its redeemable noncontrolling interest, in the accompanying consolidated statements of operations for the year ended March 31, 2023.

(E) Consolidated Vant Equity Transactions

Immunovant

In October 2022, the Company's subsidiary, Immunovant, Inc. ("Immunovant"), completed an underwritten public offering of 12,500,000 shares of its common stock (including 416,667 shares of common stock purchased by RSL) at a price to the public of \$6.00 per share, for net proceeds to Immunovant of approximately \$70.2 million after deducting underwriting discounts and commissions and offering expenses.

In October 2023, the Company's subsidiary, Immunovant, Inc., completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by the Company on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of \$38.00 per share. Concurrent with the public offering, the Company purchased 4,473,684 shares of Immunovant's common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of \$38.00 per share. The net proceeds to Immunovant were approximately \$466.7 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses. The Company's equity ownership interest in Immunovant is approximately 55% as of March 31, 2024, and the Company continues to consolidate Immunovant.

Note 11—Share-Based Compensation

(A) RSL Equity Incentive Plans

RSL has three equity incentive plans: the Roivant Sciences Ltd. 2021 Equity Incentive Plan (the "RSL 2021 EIP"), the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan (the "RSL 2015 EIP"), and the Roivant Sciences Ltd. Amended and Restated 2015 Restricted Stock Unit Plan (the "2015R Plan") (collectively, the "RSL Equity Plans"). The RSL 2021 EIP was approved and adopted in connection with the Business Combination and became effective immediately prior to closing. Since the effective date of the RSL 2021 EIP, no further stock awards have been or will be made under the RSL 2015 EIP. Additionally, no further stock awards will be made under the 2015R Plan. As of March 31, 2024, 142,055,968 of the Company's common shares were reserved for issuance under the RSL 2021 EIP. The number of common shares reserved for issuance under the RSL 2021 EIP will automatically increase on April 1 of each year 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 the board of directors in its discretion. Prior to April 1, 2024, the board of directors resolved not to increase the number of common shares reserved for issuance under the RSL 2021 EIP on April 1, 2024, but instead to defer until later this fiscal year the decision as to whether to increase the reserve by up to 5% of the common shares outstanding as of the March 31, 2024. The RSL 2021 EIP has a ten-year term. The Company's employees, directors, and consultants are eligible to receive incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock awards under the RSL 2021 EIP. At March 31, 2024, a total of 42,725,086 common shares were available for future grants under the RSL 2021 EIP.

Stock Options and Performance Stock Options

Activity for stock options and performance stock options under the RSL Equity Plans for the year ended March 31, 2024 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2023	154,271,791	\$ 7.75	6.70	\$ 280,171
Granted	4,525,962	\$ 8.89		
Exercised	(11,124,901)	\$ 4.31		
Forfeited/Canceled	(604,245)	\$ 11.17		
Options outstanding at March 31, 2024	147,068,607	\$ 8.03	5.70	\$ 499,487
Options exercisable at March 31, 2024	97,162,627	\$ 9.50	4.60	\$ 228,479

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable options and the fair value of the Company's common stock at March 31, 2024. At March 31, 2024, total unrecognized compensation expense related to non-vested stock options was approximately \$156.9 million and is expected to be recognized over a weighted-average period of approximately 2.01 years. All performance stock options have been fully expensed as of March 31, 2024.

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. No performance stock options were granted during the years ended March 31, 2024 and 2023.

Assumptions	Years Ended March 31,	
	2024	2023
Expected stock price volatility	72.22%	85.95%
Expected risk free interest rate	3.72%	2.89%
Expected term, in years	6.21	6.25
Expected dividend yield	—%	—%

Additional information regarding stock options and performance stock options is set forth below (in thousands, except per share data).

	Years Ended March 31,	
	2024	2023
Intrinsic value of options exercised	\$ 68,673	\$ 972
Grant date fair value of options vested	\$ 157,359	\$ 165,702
Weighted-average grant date fair value per share of stock options granted	\$ 5.98	\$ 2.86

Restricted Stock Units and Performance Stock Units

Activity for restricted stock units and performance stock units under the RSL Equity Plans for the year ended March 31, 2024 was as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2023	20,700,788	\$ 8.30
Granted	4,337,108	\$ 9.15
Vested	(6,839,501)	\$ 7.18
Forfeited	(1,420,184)	\$ 7.58
Non-vested balance at March 31, 2024	<u>16,778,211</u>	<u>\$ 9.04</u>

The total fair value of restricted stock units and performance stock units vested during the years ended March 31, 2024 and 2023 was \$49.1 million and \$67.6 million, respectively. Restricted stock units vest upon the achievement of time-based service requirements. The vesting of performance stock units requires that certain performance conditions are achieved during the performance period and is subject to continued service requirements.

At March 31, 2024, total unrecognized compensation expense related to non-vested restricted stock units and performance stock units was approximately \$119.9 million. Unrecognized compensation expense relating to restricted stock units and performance stock units that are deemed probable of vesting is expected to be recognized over a weighted-average period of approximately 2.23 years.

Capped Value Appreciation Rights

March 2020 CVAR Grants

Activity for capped value appreciation rights (“CVARs”) under the RSL 2015 EIP for the year ended March 31, 2024 was as follows:

	Number of CVARs	Weighted Average Grant Date Fair Value
Non-service-vested CVARs balance at March 31, 2023	1,815,441	\$ 1.19
Granted	—	\$ —
Service-vested	(1,775,667)	\$ 1.20
Forfeited	(39,774)	\$ 0.40
Non-service-vested CVARs balance at March 31, 2024	<u>—</u>	<u>\$ —</u>

The CVARs granted in March 2020 pay at settlement 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. For CVARs with the lower hurdle price of \$6.40, in the event the fair market value of a common share is greater than \$6.40 per share but less than \$9.20 per share as of the relevant date of determination (the “Knock-In Condition”), this award of CVARs will remain outstanding unless and until the knock-in condition is satisfied as of any applicable monthly measurement date thereafter before the expiration date of the CVARs. In the event any CVARs have satisfied the time-based service and liquidity event vesting requirements (“service-vested CVARs”) but have not satisfied the applicable hurdle price on an applicable measurement date, then such CVARs will be deemed to remain outstanding and the applicable award holder will be provided the right to earn such CVARs if the hurdle price is satisfied on subsequent annual “hurdle measurement dates” prior to the original expiration date of the CVARs, being March 31, 2026. The “hurdle measurement dates” are March 30 of each of years 2023 through 2026. If the hurdle price is not satisfied on any such subsequent annual hurdle measurement date prior to the expiration date of the CVARs, then the CVARs will be forfeited in their entirety on the expiration date.

As of March 31, 2024 and 2023, 31,972,222 and 30,196,555 CVARs, respectively, had met the service-vesting requirement. During the year ended March 31, 2024, 14,482,570 service-vested CVARs satisfied their applicable hurdle price and the knock-in condition, if relevant, on the applicable measurement date, and as a result, 5,366,815 common shares were issued upon their settlement. All other CVARs granted in March 2020 that remain outstanding have met the service vesting condition as of March 31, 2024 but have not satisfied their applicable hurdle price on an applicable hurdle measurement date. The total fair value of CVARs that service-vested during the years ended March 31, 2024 and 2023 was \$2.1 million and \$16.7 million, respectively. All March 2020 CVARs have been fully expensed as of March 31, 2024.

November 2021 CVAR Grants

In November 2021, the Company made one-time grants of 6,317,350 CVARs in the aggregate under the RSL 2021 EIP to eligible participants. The CVARs are eligible to vest based on the satisfaction of service-based and performance-based vesting requirements. The performance-based vesting requirement was achieved in December 2021. Vested CVARs will be settled in common shares, up to a specified cap price.

Activity for CVARs under the RSL 2021 EIP for the year ended March 31, 2024 was as follows:

	Number of CVARs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2023	3,222,645	\$ 4.89
Granted	—	\$ —
Vested	(1,247,737)	\$ 4.98
Forfeited	(192,830)	\$ 4.32
Non-vested balance at March 31, 2024	<u>1,782,078</u>	<u>\$ 4.89</u>

The total fair value of CVARs that vested during the years ended March 31, 2024 and 2023 was \$6.2 million and \$13.0 million, respectively. During the year ended March 31, 2024, 1,247,737 common shares were issued upon their settlement.

At March 31, 2024, total unrecognized compensation expense related to non-vested CVARs was approximately \$1.3 million and is expected to be recognized over a weighted-average period of approximately 1.12 years.

Separation Agreement with former Chairman

In February 2023, the Company entered into a Separation and Mutual Release Agreement with its former Chairman. Pursuant to the terms of this agreement, all non-vested performance stock options were accelerated and deemed fully vested, and the time-based service requirement for all non-vested CVARs was accelerated and deemed satisfied, in each case as of the separation date. Share-based compensation expense included in SG&A expense for the year ended March 31, 2023 includes a reversal of expense of \$20.8 million related to the modification of these awards.

(B) Employee Stock Purchase Plan

In September 2021, the Company adopted the Roivant Sciences Ltd. Employee Stock Purchase Plan (the “RSL ESPP”), which provides eligible employees, as defined by the RSL ESPP, the opportunity to purchase stock under the RSL ESPP at a price equal to 85% of the lower of the closing price on (i) the first trading day, or (ii) the last trading day of each offering period. Contributions under the RSL ESPP are limited to a maximum of 15% of an employee’s base salary during the offering period and an annual maximum of \$25 thousand. The Company opened enrollment in August 2022 for a three-month initial offering period, beginning October 2022, with additional six-month offering periods following thereafter.

During the years ended March 31, 2024 and 2023, 140,227 and 111,519 common shares were purchased and issued under the RSL ESPP, respectively. Share-based compensation expense recorded was approximately \$0.5 million and \$0.3 million for the years ended March 31, 2024 and 2023, respectively.

(C) Subsidiary Equity Incentive Plans

Certain 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. The Company recorded share-based compensation expense of \$67.0 million and \$49.0 million for the years ended March 31, 2024 and 2023, respectively, related to subsidiary EIPs. At March 31, 2024, total unrecognized compensation expense related to subsidiary equity was approximately \$119.9 million.

Note 12—Income Taxes

The income/(loss) before income taxes and the related expense (benefit) are as follows (in thousands):

	Years Ended March 31,	
	2024	2023
Income (loss) before income taxes:		
Bermuda ⁽¹⁾	\$ 5,181,194	\$ (48,547)
United States	(231,938)	(444,407)
Switzerland	(696,341)	(728,124)
Other	515	(3,756)
Total income (loss) from continuing operations before income taxes	<u>\$ 4,253,430</u>	<u>\$ (1,224,834)</u>

(1) Primarily entities which are centrally managed and controlled in the U.K. and are subject to U.K. taxes.

	Years Ended March 31,	
	2024	2023
Current taxes:		
Bermuda	\$ —	\$ —
United States	22,534	5,312
Switzerland	—	—
Other	(310)	(122)
Total current tax expense	<u>\$ 22,224</u>	<u>\$ 5,190</u>
Deferred taxes:		
Bermuda	\$ —	\$ —
United States	—	—
Switzerland	—	—
Other	—	—
Total deferred tax benefit	<u>\$ —</u>	<u>\$ —</u>
Total income tax expense	<u>\$ 22,224</u>	<u>\$ 5,190</u>

A reconciliation of income tax expense/(benefit) computed at the Bermuda statutory rate to income tax expense/(benefit) reflected in the consolidated financial statements is as follows (in thousands, except percentages):

	Year Ended March 31, 2024		Year Ended March 31, 2023	
Income tax expense/(benefit) at Bermuda statutory tax rate	\$ —	—%	\$ —	—%
Foreign rate differential ⁽¹⁾	1,155,668	27.17%	(208,440)	17.02%
Permanent disallowed IPR&D	—	—%	17,714	(1.45)%
Nondeductible/(nontaxable) changes in the fair value of investments and loss from equity method investments	15,431	0.36%	4,118	(0.34)%
Substantial shareholding exemption	(1,337,102)	(31.44)%	—	—%
Nondeductible executive compensation	19,727	0.46%	20,558	(1.68)%
Tax deficiencies (excess tax benefits) from stock-based compensation	(21,668)	(0.51)%	3,311	(0.27)%
Other permanent adjustments	40,544	0.95%	10,936	(0.89)%
Research tax credits	(24,664)	(0.58)%	(14,487)	1.18%
Valuation allowance	87,550	2.06%	157,197	(12.83)%
Reversal of certain deferred tax assets ⁽²⁾	87,262	2.06%	11,630	(0.95)%
Other	(524)	(0.01)%	2,653	(0.21)%
Total income tax expense	\$ 22,224	0.52%	\$ 5,190	(0.42)%

(1) Primarily related to operations in the U.S., Switzerland, the U.K. and other jurisdictions with statutory tax rates different than the Bermuda rate.

(2) Primarily relates to deferred tax assets associated with entities no longer included in the consolidated financial statements (i.e., sold, deconsolidated or liquidated).

The Company's effective tax rate for the years ended March 31, 2024 and 2023 was 0.52% and (0.42)%, respectively. The effective tax rate for the year ended March 31, 2024 is driven by the Company's gain on sale of Telavant net assets, which qualifies for the substantial shareholding exemption in the U.K. and consequently is not subject to the corporation income tax, as well as earnings by jurisdiction and a valuation allowance that eliminates the Company's global net deferred tax assets. The effective tax rate for the year ended March 31, 2023 is driven by the earnings by jurisdiction 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, 2024 and 2023 are as follows (in thousands):

	March 31, 2024	March 31, 2023
Deferred tax assets		
Research tax credits	\$ 45,291	\$ 37,559
Intangible assets	50,054	52,857
Capitalized research and development	32,124	37,252
Net operating loss	519,046	422,613
Share-based compensation	105,458	105,343
Lease liabilities	13,286	15,521
Other assets	19,605	25,959
Subtotal	784,864	697,104
Valuation allowance	(766,820)	(674,517)
Deferred tax liabilities		
Depreciation	(775)	(1,798)
Right-of-use assets	(10,992)	(12,959)
Other liabilities	(6,277)	(7,830)
Total deferred tax assets/(liabilities)	\$ —	\$ —

The Company has net operating losses in Switzerland, the U.S. and the U.K. in the amount of \$3,439.0 million, \$139.7 million, and \$162.6 million, respectively. The Switzerland net operating losses will expire in varying amounts between March 31, 2025 and March 31, 2031. The U.S. 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 U.K. and other net operating losses can be carried forward indefinitely as well, with an annual limitation on utilization. The Company has generated \$45.3 million of research tax credit carryforwards primarily in the U.S. and Canada, which will expire in varying amounts between March 31, 2039 and March 31, 2044.

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 \$766.8 million as of March 31, 2024, representing the portion of the deferred tax asset that is not more likely than not to be realized. For the period April 1, 2023 through March 31, 2024, the valuation allowance increased by \$92.3 million, primarily as a result of corresponding increases in our global net operating losses. 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. 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 U.K. 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 U.S., U.K., 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, 2019 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.

The Company's unrecognized tax benefit activity during the years ended March 31, 2024 and March 31, 2023 were not material to the Company's consolidated financial statements. No interest and penalties related to unrecognized tax benefits were recorded as of March 31, 2024 or March 31, 2023.

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 components of operating lease expense for the Company were as follows (in thousands):

	Years Ended March 31,	
	2024	2023
Operating lease cost	\$ 11,829	\$ 12,045
Short-term lease cost	79	1,623
Variable lease cost	1,193	2,151
Total operating lease cost	\$ 13,101	\$ 15,819

Information related to the Company's operating lease right-of-use assets and lease liabilities was as follows (in thousands, except periods and percentages):

	Year Ended March 31,	
	2024	2023
Cash paid for operating lease liabilities	\$ 13,010	\$ 13,109
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$ 1,790	\$ 4,224
	March 31, 2024	March 31, 2023
Weighted average remaining lease term (in years)	7.8	8.4
Weighted average discount rate	7.4%	7.9%

As of March 31, 2024, maturities of operating lease liabilities were as follows (in thousands):

Years Ending March 31,	
2025	\$ 10,699
2026	9,657
2027	8,852
2028	8,867
2029	8,747
Thereafter	28,565
Total lease payments	<u>75,387</u>
Less: present value adjustment	(17,843)
Less: tenant improvement allowance	(386)
Total lease liabilities	<u>\$ 57,158</u>

Note 14—Commitments and Contingencies

(A) Commitments

Long-Term Debt

The Company is obligated to make contractual payments related to its long-term debt. Refer to Note 8, “Long-Term Debt” and Note 18, “Subsequent Events” for further information.

Lease Commitments

The Company has leases, consisting primarily of real estate leases. Refer to Note 13, “Leases” for further information.

Other Commitments

The Company has entered into commitments under various asset acquisition and license agreements. Potential material future milestone payments as of March 31, 2024 pursuant to certain key asset acquisition and license agreements are as follows:

- **VTAMA/tapinarof (Dermavant):** up to CAD\$75.0 million in remaining commercial milestones to Welichem Biotech Inc., with CAD\$35.0 million payable upon VTAMA first U.S. commercial sale for atopic dermatitis and the remainder payable as first commercial sales are achieved in various countries outside of the U.S. Additional milestones are owed to NovaQuest pursuant to the NovaQuest Agreement. Refer to Note 8, “Long-Term Debt” and Note 18, “Subsequent Events” for further information.
- **Anti-FcRn franchise (Immunovant):** up to a maximum of \$420.0 million to HanAll Biopharma Co., Ltd. upon the achievement of certain development, regulatory and sales milestone events.
- **Brepocitinib (Priovant Therapeutics, Inc.):** mid tens-of-millions sales milestone payment to Pfizer if aggregate net sales in a given year exceed a mid-hundred-of-millions amount.
- **Namilumab (Kinevant Ltd.):** up to approximately \$40 million to the prior shareholders of Izana Biosciences Limited upon the achievement of certain milestones.

Royalties are also due on net sales pursuant to these agreements. The Company has further commitments not reflected above relating to other asset acquisition and license agreements entered and expects to enter into additional asset acquisition and license agreements in the future, which may require upfront payments and long-term commitments of capital resources.

Additionally, the Company enters into agreements with contract service providers to assist in the performance of its research and development 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.

In conjunction with Dermavant’s entry into the GSK Agreement in 2018, Dermavant entered into a clinical supply agreement pursuant to which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during the Company’s clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and prices. The commercial supply agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, Dermavant and GSK amended the terms of the clinical supply and commercial supply agreements which released GSK of certain commitments to supply tapinarof and released Dermavant of certain commitments to purchase tapinarof in exchange for a supplementary fee. Other supply and purchase commitments under the agreements remain in effect. In addition, Dermavant and Thermo Fisher Scientific (“TFS”) entered into a Commercial Manufacturing and Supply Agreement for which TFS agreed to provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. As of March 31, 2024, the remaining minimum purchase commitment related to these agreements was estimated to be approximately \$33.3 million.

In November 2021, the Company's subsidiary, Immunovant, entered into a Product Service Agreement ("PSA") with Samsung Biologics Co., Ltd. ("Samsung") by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. Immunovant had the right to terminate the PSA with 30 days' written notice to Samsung, exercisable no later than January 2024, in the event Immunovant decided to stop all development of, and all attempts to obtain regulatory approval for, batoclimab; subject to payment to Samsung of non-cancelable service fees and costs incurred by Samsung for all batches of batoclimab scheduled to be manufactured during the two-year period following such termination. Because efforts to develop and obtain regulatory approval for batoclimab remain ongoing, Immunovant did not exercise that early termination right and it has lapsed. As a result, Immunovant has an additional minimum obligation to purchase additional batches of batoclimab in the four-year period of 2026 through 2029. As of March 31, 2024, the remaining minimum purchase commitment related to this agreement was estimated to be approximately \$46.2 million.

Cash Bonus Program

In December 2023, the Company approved a special one-time cash retention bonus award to its employees in the aggregate amount of \$76.9 million (the "Cash Bonus Program"). In February 2024, the Company expanded this Cash Bonus Program to include an award to its Chief Financial Officer on similar terms as the other awards previously made to other employees. The Chief Financial Officer did not receive a payment from the Cash Bonus Program approved in December. This award to the Chief Financial Officer was in the aggregate amount of \$2.8 million. During the year ended March 31, 2024, the Company recognized selling, general and administrative expense and research and development expense of \$35.6 million and \$9.9 million, respectively, relating to the Cash Bonus Program. The remaining portion of \$31.0 million as of March 31, 2024 will be recognized over the applicable service period of the award.

(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.

Acuitas Declaratory Judgment Action

In March 2022, Acuitas Therapeutics Inc. ("Acuitas") filed a lawsuit in the U.S. District Court for the Southern District of New York ("SDNY") against two of the Company's affiliates, Genevant and Arbutus, seeking a declaratory judgment that certain patents held by Arbutus and licensed by Genevant are not infringed by the manufacture, use, offer for sale, sale or importation into the U.S. of COMIRNATY, Pfizer's and BioNTech's vaccine for COVID-19 and are otherwise invalid. On September 6, 2022, Acuitas filed a First Amended Complaint. In response, on October 4, 2022, Genevant and Arbutus filed a motion to dismiss the first amended complaint for lack of a controversy and supporting brief. Briefing on this motion was completed in mid-November. On August 4, 2023, Acuitas voluntarily dismissed the action in the SDNY and re-filed a complaint in the U.S. District Court for the District of New Jersey. On October 13, 2023, Genevant and Arbutus filed a motion to dismiss the re-filed complaint. In May 2024, the court dismissed the complaint against Genevant and Arbutus. Acuitas may appeal the dismissal. Each of Genevant and Arbutus intends to continue to vigorously defend the case, to the extent Acuitas pursues an appeal.

(C) Indemnification Agreements

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. The Company also indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits. The maximum amount of potential future indemnification is unlimited; however, the Company currently maintains director and officer liability insurance, which may cover certain liabilities arising from the Company's obligation to indemnify its directors and officers. To date, the Company has not incurred any material costs related to these indemnification obligations and has not accrued any liabilities related to such obligations in the consolidated financial statements as of March 31, 2024 and 2023.

Note 15—Earn-Out Shares, Public Warrants and Private Placement Warrants

Earn-Out Shares

In connection with the Business Combination, the Company issued the following:

- a. 2,033,591 common shares to Patient Square Capital LLC (the “MAAC Sponsor”) and 10,000 common shares issued to each of MAAC’s independent directors (collectively, the “20% Earn-Out Shares”), which will vest if the closing price of the Company’s 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 common shares issued to the MAAC Sponsor and 5,000 common shares issued to each of MAAC’s independent directors (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 the Company’s common shares is greater than or equal to \$20.00 over any twenty out of thirty trading day period during the Vesting Period (as defined below).
- c. The remaining number of common shares issued to the MAAC Sponsor and each of MAAC’s independent directors are not subject to the vesting conditions described above.

The Vesting Period commenced on November 9, 2021 and ends no later than September 30, 2026 (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 require liability classification and are classified as “Liability instruments measured at fair value” on the 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 consolidated statements of operations. As of March 31, 2024, no Earn-Out Shares have vested.

Public Warrants and Private Placement Warrants

Immediately following the Business Combination, the Company had 10,214,365 outstanding warrants for the purchase of one of the Company’s common shares, which were held by the MAAC Sponsor at an exercise price of \$11.50 (the “Private Placement Warrants”), and 20,535,896 outstanding warrants for the purchase of one of the Company’s common shares, which were held by MAAC’s shareholders at an exercise price of \$11.50 (the “Public Warrants” and, together with the Private Placement Warrants, the “Warrants”). Pursuant to the Warrant Agreement, dated October 6, 2020, by and between MAAC and Continental Stock Transfer & Trust Company, as predecessor warrant agent, as modified by the Warrant Assumption Agreement, dated September 30, 2021, by and among MAAC, the Company and American Stock Transfer & Trust Company, LLC as successor warrant agent (as modified, the “Warrant Agreement”), the Warrants became exercisable 30 days following the completion of the Business Combination and would expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

Prior to their settlement, the Warrants required liability classification and were classified as “Liability instruments measured at fair value” on the consolidated balance sheets. The Private Placement Warrants liability and Public Warrants liability were subject to remeasurement with changes in fair value recognized in the Company’s statements of operations. The Warrants were remeasured immediately prior to settlement. These remeasurements were recognized in “Change in fair value of debt and liability instruments” in the accompanying consolidated statements of operations.

On August 2, 2023, the Company announced that it would redeem all Warrants that remained outstanding on September 1, 2023 (the “Redemption Date”).

Under the terms of the Warrant Agreement, the Company was entitled to redeem the Public Warrants at a redemption price of \$0.10 per Public Warrant because the last reported sales price (the “Reference Value”) of the Company’s common shares was at least \$10.00 per share for any twenty (20) trading days within the thirty (30) trading-day period ending on the third trading day prior to the date on which RSL gave a Notice of Redemption. In addition, because the Reference Value was less than \$18.00 per share, the outstanding Private Placement Warrants were also required to be concurrently called for redemption on the same terms as the outstanding Public Warrants. This share price performance requirement was satisfied as of July 28, 2023.

Prior to the Redemption Date, Warrant holders were permitted to exercise the Warrants (i) for cash, at an exercise price of \$11.50 per common share, or (ii) on a “cashless basis” whereby, in lieu of paying the Company the \$11.50 exercise price per common share, the surrendering holder would receive approximately 0.2495 common shares per Warrant as determined in accordance with the terms of the Warrant Agreement.

Of the 20,475,875 Public Warrants that were outstanding as of June 30, 2023, 397 Public Warrants were exercised for cash at an exercise price of \$11.50 per common share in exchange for an aggregate of 397 common shares and 20,061,507 were exercised on a cashless basis in exchange for an aggregate of 5,005,531 common shares. The remaining 413,971 unexercised Public Warrants were redeemed at the \$0.10 redemption price. In addition, all of the Private Placement Warrants were exercised on a cashless basis in exchange for an aggregate of 2,548,621 common shares.

Note 16—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, 2024 and 2023, by level, within the fair value hierarchy (in thousands):

	As of March 31, 2024				As of March 31, 2023			
	Level 1	Level 2	Level 3	Balance as of March 31, 2024	Level 1	Level 2	Level 3	Balance as of March 31, 2023
Assets:								
Money market funds	\$ 6,312,288	\$ —	\$ —	\$ 6,312,288	\$ 1,496,726	\$ —	\$ —	\$ 1,496,726
Investment in Datavant Class A units	—	—	147,526	147,526	—	—	178,579	178,579
Investment in Arbutus common shares	100,227	—	—	100,227	117,708	—	—	117,708
Other investments	—	—	—	—	8,030	—	—	8,030
Total assets at fair value	\$ 6,412,515	\$ —	\$ 147,526	\$ 6,560,041	\$ 1,622,464	\$ —	\$ 178,579	\$ 1,801,043
Liabilities:								
Debt issued by Dermavant to NovaQuest	\$ —	\$ —	\$ 210,371	\$ 210,371	\$ —	\$ —	\$ 207,640	\$ 207,640
Liability instruments measured at fair value ⁽¹⁾	—	—	25,737	25,737	29,895	—	33,651	63,546
Total liabilities at fair value	\$ —	\$ —	\$ 236,108	\$ 236,108	\$ 29,895	\$ —	\$ 241,291	\$ 271,186

(1) At March 31, 2024, Level 3 includes the fair value of the Earn-Out Shares of \$22.0 million and other liability instruments issued of \$3.7 million. At March 31, 2023, Level 1 includes the fair value of the Public Warrants of \$29.9 million, and Level 3 includes the fair value of the Earn-Out Shares of \$15.2 million, Private Placement Warrants of \$15.2 million, and other liability instruments issued of \$3.3 million.

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, 2024 and 2023.

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 consolidated 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 years ended March 31, 2024 and 2023 were as follows (in thousands):

Balance at March 31, 2022	\$	193,963
Changes in fair value of investment in Datavant, included in net loss		(15,384)
Balance at March 31, 2023		178,579
Changes in fair value of investment in Datavant, included in net loss		(31,053)
Balance at March 31, 2024	\$	147,526

The changes in fair value of the Level 3 liabilities during the years ended March 31, 2024 and 2023 were as follows (in thousands):

Balance at March 31, 2022	\$	204,293
Fair value of liability instrument issued		248
Payments related to long-term debt		(29,375)
Changes in fair value of debt and liability instruments, included in net loss		66,125
Balance at March 31, 2023		241,291
Payments related to long-term debt		(29,374)
Exercise of Private Placement Warrants		(28,090)
Changes in fair value of debt and liability instruments, included in net loss		52,281
Balance at March 31, 2024	\$	236,108

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 the income approach and implementation of the option pricing method ("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 March 31, 2024	As of March 31, 2023
Volatility	90.0%	100.0%
Risk-free rate	4.86%	4.02%

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of March 31, 2024 and 2023 represents the fair value of amounts payable to NovaQuest and was estimated based upon present value discounted quarterly payments and a Monte Carlo simulation model under the income approach for expected future payments through 2032. 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. The NovaQuest Agreement, along with the Credit Facility and RIPSAs, was amended in May 2024. Refer to Note 18, "Subsequent Events" for details regarding the amendments.

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 15, “Earn-Out Shares, Public Warrants and Private Placement Warrants” 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 March 31, 2024	As of March 31, 2023
Volatility	63.2%	79.9%
Risk-free rate	4.50%	3.76%

As of March 31, 2024 and 2023, the fair value of the Earn-Out Shares was \$22.0 million and \$15.2 million, respectively. Earn-Out Shares were included in “Liability instruments measured at fair value” in the accompanying consolidated balance sheets.

Private Placement Warrants

Prior to their settlement, 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 15, “Earn-Out Shares, Public Warrants and Private Placement Warrants” and the added restriction by which the Company could not redeem the Private Placement Warrants if the Reference Value was 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 March 31, 2023
Volatility	50.5%
Risk-free rate	3.76%
Term (in years)	3.50

In August 2023, the Company announced that it would redeem all Warrants that remained outstanding on September 1, 2023. All of the Private Placement Warrants were exercised at that time. As of March 31, 2023, the fair value of the Private Placement Warrants was \$15.2 million, which was included in “Liability instruments measured at fair value” in the accompanying consolidated balance sheets.

Note 17—Net Income (Loss) per Common Share

Basic net income (loss) per common share is computed by dividing net income (loss) attributable to Roivant Sciences Ltd. by the weighted-average number of common stock outstanding during the period. Diluted net income (loss) 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 stock equivalents is anti-dilutive. For the year ended March 31, 2023, 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.

As of March 31, 2024 and 2023, the following potentially dilutive common stock equivalents were excluded from the computation of diluted net income (loss) per common share because including them would have been anti-dilutive:

	March 31, 2024	March 31, 2023
Stock options and performance stock options	54,648,258	154,271,791
Restricted stock units and performance stock units (non-vested)	5,422,465	20,700,788
March 2020 CVARs ⁽¹⁾	17,548,368	32,011,996
November 2021 CVARs (non-vested)	249,120	3,222,645
Restricted common stock (non-vested)	255,911	689,026
Earn-Out Shares (non-vested)	3,080,387	3,080,387
Private Placement Warrants	—	10,214,365
Public Warrants	—	20,475,875
Other stock based awards and instruments issued	3,924,305	6,122,842

(1) Refer to Note 11, “Share-Based Compensation” for details regarding settlement of CVARs.

Note 18—Subsequent Events

(A) Share Repurchase Program

The Company’s board of directors has authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to \$1.5 billion (excluding fees and expenses). The repurchase program is funded by available cash and cash equivalents on hand and does not have an expiration date. Pursuant to the share repurchase program, on April 2, 2024, the Company entered into a share repurchase agreement with Sumitomo to repurchase all 71,251,083 common shares held by Sumitomo at a purchase price per share of \$9.10, for an aggregate purchase price of approximately \$648.4 million. The repurchase transaction with Sumitomo was completed on April 2, 2024.

(B) Debt Renegotiation

On May 24, 2024, Dermavant entered into amendments to (i) the NovaQuest Agreement (the “NovaQuest Agreement Amendment”), (ii) the Credit Facility (the “Credit Facility Amendment”), and (iii) the RIPSAs (the “RIPSAs Amendment” and collectively with the NovaQuest Agreement Amendment and the Credit Facility Amendment, the “Amendments”).

The NovaQuest Agreement Amendment provides for the elimination of fixed quarterly cash payments totaling \$176.3 million that would have been due and payable following regulatory approval of tapinarof in the U.S. for atopic dermatitis, if approved. In addition, the NovaQuest Agreement Amendment (i) eliminates cash payments of up to \$141.0 million to NovaQuest that would have been due and payable upon achievement of certain commercial milestones by Dermavant and (ii) amends the timing of remaining cash payments, which now total \$122.5 million in aggregate, to be paid between the fiscal years ending March 31, 2025 and March 31, 2029.

The Credit Agreement Amendment provides for an extension of the maturity date of the Credit Facility from May 2026 to May 2028 and an increase in the interest rate payable on borrowings under the Credit Facility from 10% to 12.25% per annum.

The RIPSAs Amendment provides for, among other things, a near-term cap on the royalties currently payable equal to \$6 million per fiscal year for each of the fiscal years ended March 31 2025, 2026 and 2027. The RIPSAs Amendment did not otherwise amend the amount of the royalty payable, which is based on a capped single-digit revenue interest in net sales of VTAMA for all dermatological indications in the U.S., up to a cap of \$344 million.

The Amendments also includes certain other modifications to non-economic terms of the NovaQuest Agreement, including certain representations and covenants relating to the continued validity of, and performance by RSL, under an equity commitment letter (the “Equity Commitment Letter”) entered into in conjunction with the Amendments on May 24, 2024. Under the Equity Commitment Letter, RSL has agreed to contribute \$195 million (the “Commitment”) to Dermavant in exchange for convertible preferred shares with a 1.5 times liquidation preference on invested capital.

As consideration for entering into the Amendments, Dermavant issued common shares to NovaQuest and the holders of the RIPSAs in an aggregate amount equal to approximately 13.2% of Dermavant’s issued and outstanding common and preferred shares (on an as converted basis) pursuant to subscription agreements (the “Subscription Agreements”). The common shares include certain antidilution top-up rights tied to RSL’s Commitment. The Amendments, together with the Equity Commitment Letter and the Subscription Agreements, constitute the “Debt Renegotiation.”

As of closing of the Debt Renegotiation, RSL owned approximately 87% of Dermavant’s issued and outstanding common and preferred shares.

The Company is in the process of evaluating the accounting impact as a result of the Debt Renegotiation.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024, the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2024 at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined under Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of March 31, 2024. In making this assessment, management used the criteria set forth in the Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of March 31, 2024, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of March 31, 2024, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Roivant Sciences Ltd.

Opinion on Internal Control Over Financial Reporting

We have audited Roivant Sciences Ltd.'s internal control over financial reporting as of March 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Roivant Sciences Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of March 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of March 31, 2024 and 2023, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and redeemable noncontrolling interest and cash flows for each of the two years in the period ended March 31, 2024, and the related notes and our report dated May 30, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Iselin, New Jersey

May 30, 2024

ITEM 9B. OTHER INFORMATION

As previously disclosed, on May 24, 2024, Dermavant Sciences Ltd. (“DSL”), a subsidiary of the Company, and certain of DSL’s wholly-owned subsidiaries (together with DSL, “Dermavant”), entered into a series of agreements to renegotiate DSL’s existing debt obligations and reduce its potential cash payments due under these obligations by over \$300 million in aggregate, of which an expected reduction of approximately \$225 million would be achieved over the next three fiscal years (the “Debt Renegotiation”).

As part of the Debt Renegotiation, Dermavant entered into amendments to (i) the Revenue Interest Purchase and Sale Agreement dated as of May 14, 2021 (as amended from time to time, 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 “RIPSA Purchasers”), together with U.S. Bank Trust Company (as successor in interest to U.S. Bank National Association), as collateral agent, (ii) the Credit Agreement dated as of May 14, 2021 (as amended from time to time, the “Credit Agreement”) with XYQ Luxco, as lender, and U.S. Bank Trust Company (as successor in interest to U.S. Bank National Association), as collateral agent, and (iii) the Funding Agreement dated as of July 10, 2018 (as amended from time to time, the “NovaQuest Agreement”) with NovaQuest Co-Investment Fund VIII, L.P. (“NovaQuest”), as described below.

In addition, as part of the Debt Renegotiation, (i) Roivant entered into an equity commitment letter (the “Equity Commitment Letter”) pursuant to which Roivant has agreed to contribute \$195 million to DSL in exchange for DSL issuing Roivant convertible preferred shares with a liquidation preference equal to 1.5 times its invested capital, and (ii) DSL issued each of the RIPSA Purchasers and NovaQuest common shares in an aggregate amount equal to approximately 13.2% of DSL’s issued and outstanding common and preferred shares (on an as converted basis), which common shares include certain antidilution top-up rights tied to Roivant’s equity commitment. At closing of the Debt Renegotiation and giving effect to the funding by Roivant of the full \$195 million preferred equity commitment made to DSL, Roivant will own approximately 87% of DSL’s issued and outstanding common and preferred shares and approximately 82% of DSL on a fully-diluted basis, inclusive of issued but unexercised warrants and options and restricted stock units held by current and former employees and other service providers (for purposes of this calculation, assuming no future incentive equity grants).

Amendment to the RIPSA

On May 24, 2024, Dermavant entered into an amendment to the RIPSA (the “RIPSA Amendment”), which provides for, among other things, a near-term cap on the royalties currently payable to the RIPSA Purchasers, equal to \$6 million per fiscal year for each of the fiscal years ended March 31, 2025, 2026 and 2027. The RIPSA Amendment did not otherwise amend the amount of the royalty payable to the RIPSA Purchasers, which is based on a capped single-digit revenue interest in net sales of VTAMA for all dermatological indications in the U.S., up to a cap of \$344 million. The RIPSA Amendment also includes certain other modifications to non-economic terms of the RIPSA, including certain representations and covenants relating to the continued validity of, and performance by Roivant under, the Equity Commitment Letter.

Amendment to the Credit Agreement

On May 24, 2024, Dermavant entered into an amendment to the Credit Agreement (the “Credit Agreement Amendment”), which provides for an extension of the maturity date of the Credit Agreement from May 2026 to May 2028 and an increase in the interest rate payable on borrowings under the Credit Agreement from 10% to 12.25% per annum. The Credit Agreement Amendment also provides that Dermavant has the option to prepay the Credit Agreement in whole or in part, subject to (i) until May 2025, 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 2025 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 2025 to May 2026, a prepayment premium of 5.0% of the principal amount being repaid, and (iii) from May 2026 to May 2027, a prepayment premium of 2.5% of the principal amount being repaid. From May 2027 through maturity, the Credit Agreement may be prepaid in whole or in part without a prepayment premium. All other material terms of the Credit Agreement remain substantially the same. The Credit Agreement Amendment also includes certain other modifications to non-economic terms of the Credit Agreement, including certain representations and covenants relating to the continued validity of, and performance by Roivant under, the Equity Commitment Letter.

Amendment to the NovaQuest Agreement

On May 24, 2024, Dermavant entered into an amendment to the NovaQuest Agreement (the “NovaQuest Agreement Amendment” and, together with the RIPSA Amendment and the Credit Agreement Amendment, the “Amendments”). The NovaQuest Agreement Amendment provides for the elimination of fixed quarterly payments totaling \$176.3 million that would have been due and payable following regulatory approval of tapinarof in the U.S. for atopic dermatitis, if approved. In addition, the NovaQuest Agreement Amendment (i) eliminates payments of up to \$141.0 million to NovaQuest that would have been due and payable upon achievement of certain commercial milestones by Dermavant and (ii) amends the timing of remaining cash payments, which now total \$122.5 million in aggregate, to be paid between the fiscal years ending March 31, 2025 and March 31, 2029. The NovaQuest Agreement Amendment also includes certain other modifications to non-economic terms of the NovaQuest Agreement, including certain representations and covenants relating to the continued validity of, and performance by Roivant under, the Equity Commitment Letter.

The foregoing descriptions of the Amendments are not complete and are qualified in their entirety by reference to the full text of the Amendments, copies of which will be filed as exhibits to Roivant’s next quarterly report on Form 10-Q filed with the SEC and will be publicly available.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2024.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at investor.roivant.com/corporate-governance. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The Shareholders required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2024.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2024.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2024.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2024.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

For a list of the consolidated financial statements included herein, see “Index to Consolidated Financial Statements” under Part I, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibits

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
2.1*	Business Combination Agreement, dated as of May 1, 2021, by and among Montes Archimedes Acquisition Corp., Roivant Sciences Ltd. and Rhine Merger Sub, Inc.	10-K	001-40782	2.1	June 28, 2022
2.2#*	Agreement and Plan of Merger, dated as of February 2, 2021, by and among Roivant Sciences Ltd., Silicon Insite, Inc., Silicon TX China, Silicon Therapeutics, LLC and Silicon SWAT, Inc.	S-4/A	333-256165	2.2	July 1, 2021
2.3*	Transaction Agreement, dated as of October 31, 2019, by and among Sumitomo Dainippon Pharma Co., Ltd., Vant Alliance Ltd., Roivant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd. and Spirovent Sciences Ltd.	SC 13D/A	—	7.04	November 4, 2019
2.4#*	Asset Purchase Agreement, dated as of July 10, 2018, by and among GlaxoSmithKline Intellectual Property Development Ltd., Glaxo Group Limited and Dermavant Sciences GmbH	S-4	333-256165	2.6	May 14, 2021
2.5#*	Asset Purchase Agreement, dated as of May 29, 2012, by and between Glaxo Group Limited and Welicem Biotech Inc.	S-4	333-256165	2.7	May 14, 2021

2.6#*	First Amendment to the Asset Purchase Agreement, dated as of August 31, 2012, by and between Glaxo Group Limited and Welichem Biotech, Inc.	S-4	333-256165	2.8	May 14, 2021
2.7*	Amendment No. 1 to the Business Combination Agreement, dated June 9, 2021, by and among Montes Archimedes Acquisition Corp., Roivant Sciences Ltd. and Rhine Merger Sub, Inc.	10-K	001-40782	2.9	June 28, 2022
2.8#**	Stock Purchase Agreement, by and among Roche Holdings, Inc., Roivant Sciences Ltd., Pfizer Inc. and Telavant Holdings, Inc., dated as of October 22, 2023	10-Q	001-40782	2.1	November 13, 2023
3.1*	Memorandum of Association of Roivant Sciences Ltd.	S-4/A	333-256165	3.1	July 1, 2021
3.2*	Amended and Restated Bye-laws of Roivant Sciences Ltd.	8-K	001-40782	3.1	October 1, 2021
4.1*	Specimen Ordinary Share Certificate of Roivant Sciences Ltd.	S-4/A	333-256165	4.5	August 3, 2021
4.2*	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-40782	4.5	June 28, 2023
10.1*	Third Amended and Restated Registration Rights Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd. and the parties thereto	10-K	001-40782	10.1	June 28, 2022
10.2*	Sponsor Support Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	10-K	001-40782	10.3	June 28, 2022
10.3*	Form of Transaction Support Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp. and certain shareholders of Roivant Sciences Ltd.	10-K	001-40782	10.4	June 28, 2022
10.4*	Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and Montes Archimedes Acquisition Corp.	8-K	001-39597	10.1	October 13, 2020
10.5#*	License Agreement, dated as of December 19, 2017, by and between HanAll Biopharma Co., Ltd. and Roivant Sciences GmbH	8-K	001-38906	10.6	December 20, 2019
10.6#*	Collaboration and License Agreement, dated as of January 15, 2020, by and between Dermavant Sciences GmbH and Japan Tobacco Inc.	S-4	333-256165	10.7	May 14, 2021

10.7#*	Clinical Manufacturing and Supply Agreement, dated August 20, 2018, by and between Dermavant Sciences GmbH and GlaxoSmithKline Trading Services Limited	S-4	333-256165	10.8	May 14, 2021
10.8#*	Commercial Manufacturing and Supply Agreement, dated April 1, 2019, by and between Dermavant Sciences GmbH and GlaxoSmithKline Trading Services Limited	S-4	333-256165	10.9	May 14, 2021
10.9#*	Funding Agreement, dated as of July 10, 2018, by and between Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P.	S-4	333-256165	10.10	May 14, 2021
10.10#*	First Amendment to Funding Agreement, dated as of October 11, 2018, by and between Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P.	S-4	333-256165	10.11	May 14, 2021
10.11#*	Cross License Agreement, dated as of April 11, 2018, by and between Genevant Sciences Ltd. and Arbutus Biopharma Corporation	10-Q	001-34949	10.3	August 7, 2020
10.12#*	First Amendment to Cross License Agreement, dated as of June 27, 2018, by and among Genevant Sciences Ltd., Genevant Sciences GmbH and Arbutus Biopharma Corporation	10-Q	001-34949	10.4	August 7, 2020
10.13#*	Second Amendment to Cross License Agreement, dated as of June 27, 2018, by and among Genevant Sciences Ltd., Genevant Sciences GmbH and Arbutus Biopharma Corporation	10-Q	001-34949	10.5	August 7, 2020
10.14*	Form of Indemnity Agreement	S-4/A	333-256165	10.24	July 1, 2021
10.15*^	Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	S-4	333-256165	10.25	May 14, 2021
10.16*^	Roivant Sciences Ltd. 2021 Equity Incentive Plan	S-8	333-260173	99.1	October 8, 2021
10.17*^	Executive Employment Agreement between Roivant Sciences, Inc. and Matthew Gline, dated as of May 14, 2021	S-4	333-256165	10.28	May 14, 2021
10.18*^	Executive Employment Agreement between Roivant Sciences, Inc. and Eric Venker, dated as of May 14, 2021	S-4	333-256165	10.29	May 14, 2021
10.19#*	Credit Agreement by and among Dermavant Sciences Ltd., Dermavant Holdings Limited, Dermavant Sciences IRL Limited, Dermavant Sciences GmbH, certain subsidiaries of Dermavant Sciences Ltd., XYQ Luxco S.A.R.L. and U.S. Bank National Association, as collateral agent, dated as of May 14, 2021	S-4/A	333-256165	10.31	July 1, 2021
10.20#*	Revenue Interest Purchase and Sale Agreement by and among Dermavant Sciences GmbH, certain purchasers and U.S. Bank National Association as collateral agent, dated as of May 14, 2021	S-4/A	333-256165	10.32	July 1, 2021
10.21*	Amendment No. 1 to the Support Agreement, dated as of June 9, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	10-K	001-40782	10.28	June 28, 2022

10.22*	Amendment No. 2 to the Support Agreement, dated as of September 30, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	8-K	001-40782	10.1	October 1, 2021
10.23*^	Amended & Restated Roivant Sciences Ltd. Employee Stock Purchase Plan	10-K	001-40782	10.27	June 28, 2023
10.24##*	Third Amendment to Cross License Agreement, dated December 9, 2021, by and between Genevant Sciences GmbH and Arbutus Biopharma Corporation	S-1	333-261853	10.37	December 22, 2021
10.25#†*	Exclusive License Agreement, dated as of November 24, 2021, by and between Eisai Co. Ltd and Pharmavant 7 GmbH	10-Q	001-40782	10.1	February 14, 2022
10.26#†*	Investor Rights Agreement, dated as of September 13, 2021, by and among Priovant Holdings, Inc., Roivant Sciences Ltd. and Pfizer Inc.	10-K	001-40782	10.36	June 28, 2022
10.27#†*	License and Collaboration Agreement, dated as of September 13, 2021, by and between Pfizer Inc. and Priovant, Inc.	10-K	001-40782	10.37	June 28, 2022
10.28#*	Amendment No. 1 to License and Collaboration Agreement, dated as of June 10, 2022, by and between Pfizer Inc. and Priovant, Inc.	10-K	001-40782	10.38	June 28, 2022
10.29*^	Employment Agreement between Roivant Sciences, Inc. and Mayukh Sukhatme, dated as of May 19, 2020	S-1/A	333-26	10.39	July 28, 2022
10.30#†*	Partial Termination and Supplementary Fee Agreement relating to the Clinical Supply Agreement and Commercial Supply Agreement, dated as of July 25, 2022, by and between GlaxoSmithKline Trading Services Limited and Dermavant Sciences GmbH	10-Q	001-40782	10.1	November 14, 2022
10.31#†*	Master Commercial Manufacturing and Supply Agreement, dated as of July 1, 2022, by and between Dermavant Sciences GmbH and Thermo Fisher Scientific Cork Limited	10-Q	001-40782	10.2	November 14, 2022
10.32*	Form of Stock Option Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.39	June 28, 2023
10.33*	Form of Restricted Stock Unit Award Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.40	June 28, 2023
10.34*	Form of Performance Option Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.41	June 28, 2023
10.35*	Form of Capped Value Appreciation Right Award Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.42	June 28, 2023

10.36*	Form of Stock Option Grant Notice under the Roivant Sciences Ltd. 2021 Equity Incentive Plan	10-K	001-40782	10.43	June 28, 2023
10.37*	Form of Restricted Stock Unit Award Grant Notice under the Roivant Sciences Ltd. 2021 Equity Incentive Plan	10-K	001-40782	10.44	June 28, 2023
10.38#	Master Services Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated April 30, 2021	10-Q	001-38906	10.2	February 4, 2022
10.39#	Product Service Agreement, between Samsung Biologics Co., Ltd. and Immunovant Sciences GmbH, dated November 17, 2021	10-Q	001-38906	10.3	February 4, 2022
<u>21.1</u>	List of Subsidiaries of Roivant Sciences Ltd.	—	—	—	Filed herewith
<u>23.1</u>	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm of Roivant Sciences Ltd.	—	—	—	Filed herewith
24.1	Power of Attorney (included on signature page)	—	—	—	Filed herewith
<u>31.1</u>	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
<u>31.2</u>	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
<u>32.1</u>	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
<u>32.2</u>	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
<u>97</u>	Roivant Sciences Ltd. Compensation Recoupment Policy	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	Filed herewith

- # Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to Roivant Sciences Ltd. if publicly disclosed.
- † Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.
- * Previously filed.
- ** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management’s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed “filed” for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.
- ^ Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K pursuant to Item 15(b).

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Roivant Sciences Ltd.

Date: May 30, 2024

By: /s/ Matt Maisak

Name: Matt Maisak

Title: Authorized Signatory

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard Pulik, Jo Chen and Matt Maisak, as their true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Matthew Gline</u> Matthew Gline	Chief Executive Officer and Director (Principal Executive Officer)	May 30, 2024
<u>/s/ Richard Pulik</u> Richard Pulik	Chief Financial Officer (Principal Financial Officer)	May 30, 2024
<u>/s/ Rakhi Kumar</u> Rakhi Kumar	Chief Accounting Officer (Principal Accounting Officer)	May 30, 2024
<u>/s/ Mayukh Sukhatme</u> Mayukh Sukhatme	President and Chief Investment Officer and Director	May 30, 2024
<u>/s/ Keith Manchester</u> Keith Manchester	Director	May 30, 2024
<u>/s/ Ilan Oren</u> Ilan Oren	Director	May 30, 2024
<u>/s/ Daniel Gold</u> Daniel Gold	Director	May 30, 2024
<u>/s/ Melissa Epperly</u> Melissa Epperly	Director	May 30, 2024
<u>/s/ Meghan FitzGerald</u> Meghan FitzGerald	Director	May 30, 2024
<u>/s/ James C. Momtazee</u> James C. Momtazee	Director	May 30, 2024

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