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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

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.)
Suite 1, 3rd Floor **11-12 St. James's Square** **London SW1Y 4LB** **United Kingdom** (Address of principal executive offices)	**Not Applicable** (Zip Code)

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

Not Applicable
(Former Name, former address and former fiscal year, if changed since last report)

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, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Market**
Redeemable Warrants, each whole warrant exercisable for one Common Share at an exercise price of $11.50 per share	**ROIVW**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 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. (Check one):

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of February 9, 2022, the registrant had 692,072,184 common shares, par value $0.0000000341740141 per share, outstanding (the "Common Shares").

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Where You Can Find More Information

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), filings we make with the Securities and Exchange Commission (the "SEC"), our corporate twitter account (@Roivant), other social media platforms, webcasts, press releases and conference calls. Similarly, our subsidiary Immunovant, Inc. may announce material business and financial information to its investors using its investor relations website (https://immunovant.com/investors), filings it makes with the SEC, social media platforms, webcasts, press releases and conference calls. We and our public company subsidiaries use these mediums to communicate with our and our public company subsidiaries' shareholders and the public about our company, our subsidiaries, our product candidates and other matters. It is possible that the information that we make available in this manner may be deemed to be material information. We therefore encourage investors and others interested in our company and our public company subsidiaries to review this information.

The above-referenced information is not incorporated by reference into this filing and the website addresses and Twitter account name are provided only as inactive textual references.

Summary Risk Factors

You should consider carefully the risks described under "Risk Factors" in Part II, Item 1.A of this Quarterly Report on Form 10-Q. 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 may make it difficult for us to execute on our business model and for you to assess our future viability.
- We will likely incur significant operating losses for the foreseeable future and may never achieve or maintain profitability.
- The ongoing global pandemic resulting from the outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and pre-clinical studies.
- We may not be successful in our efforts to acquire, in-license or discover new product candidates.
- Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment approaches, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.
- We face risks associated with the Vant structure.
- Clinical trials and pre-clinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or pre-clinical studies on the expected timelines, if at all.
- Our approach to the discovery and development of product candidates from our targeted protein degradation platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from this platform.
- Certain of our product candidates, including our gene therapy product candidates, are novel, complex and difficult to manufacture.
- Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulator may delay, limit or deny approval.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.

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

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

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains statements, including matters discussed under Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations, Part II, Item 1. Legal Proceedings, Part II, Item 1A. Risk Factors 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 Quarterly Report on Form 10-Q are based on our current expectations and beliefs concerning future developments and their potential effects on us taking into account information currently available to us. There can be no assurance that future developments affecting us will be those that we have anticipated. Should one or more of these risks or uncertainties materialize, they could cause our actual results to differ materially from the forward-looking statements. Some factors that could cause actual results to differ include, but are not limited to risk associated with:

- our limited operating history and risks involved in biopharmaceutical product development;
- the fact that we will likely incur significant operating losses for the foreseeable future;
- the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) on our business (including our clinical trials and pre-clinical studies), operations and financial condition and results;
- our ability to acquire, in-license or discover new product candidates;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- clinical trials and pre-clinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- the unproven nature of our approach to the discovery and development of product candidates from our targeted protein degradation platform;
- the novelty, complexity and difficulty of manufacturing certain of our product candidates, including any manufacturing problems that result in delays in development or commercialization of our product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials and/or clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- changes in interim, top-line and/or preliminary data from our clinical trials changing as more data becoming available or being delayed due to audit and verification process;
- changes in product manufacturing or formulation that could lead to the incurrence of costs or delays;
- the failure of any third party we contract with to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable requirements;
- the fact that obtaining approvals for new drugs is a lengthy, extensive, expensive and unpredictable process that may end with our inability to obtain regulatory approval by the FDA or other regulatory agencies in other jurisdictions;
- the failure of our clinical trials to demonstrate substantial evidence of the safety and efficacy of product candidates, including, but not limited to, scenarios in which our product candidates may cause adverse effects that could delay regulatory approval, discontinue clinical trials, limit the scope of approval or generally result in negative media coverage of us;
- our inability to obtain regulatory approval for a product candidate in certain jurisdictions, even if we are able to obtain approval in certain other jurisdictions;
- our ability to effectively manage growth and to attract and retain key personnel;
- any business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally;
- our ability to obtain and maintain patent and other intellectual property protection for our technology and product candidates;
- the inadequacy of patent terms and their scope to protect our competitive position;
- the failure to issue (or the threatening of their breadth or strength of protection) or provide meaningful exclusivity for our product candidates or any future product candidate of our patent applications that we hold or have in-licensed;
- the fact that we do not currently and may not in the future own or license any issued composition of matter patents covering certain of our product candidates and our inability to be certain that any of our other issued patents will provide adequate protection for such product candidates;
- the fact that our largest shareholders (and certain members of our management team) own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval;
- the outcome of any legal proceedings that may be instituted against us in connection with the Business Combination and related transactions;
- 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 II, 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 Quarterly Report on Form 10-Q, 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

ROIVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share and per share amounts)

	December 31, 2021	March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 2,214,283	$ 2,055,044
Restricted cash	2,916	77,701
Other current assets	70,334	54,250
Total current assets	2,287,533	2,186,995
Property and equipment, net	21,606	14,749
Operating lease right-of-use assets	61,682	62,279
Restricted cash, net of current portion	8,936	8,931
Investments measured at fair value	398,743	188,978
Long-term investment	—	100,563
Other assets	20,875	27,197
Total assets	$ 2,799,375	$ 2,589,692
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 24,358	$ 20,550
Accrued expenses	112,679	76,936
Operating lease liabilities	11,241	12,313
Deferred consideration liability	—	100,000
Other current liabilities	12,435	9,162
Total current liabilities	160,713	218,961
Liability instruments measured at fair value	94,600	67,893
Operating lease liabilities, noncurrent	62,091	62,384
Long-term debt (includes $171,900 and $150,100 accounted for under the fair value option at December 31, 2021 and March 31, 2021, respectively)	204,042	170,280
Other liabilities	8,176	8,169
Total liabilities	529,622	527,687
Commitments and contingencies (Note 12)		
Redeemable noncontrolling interest	22,491	22,491
Shareholders' equity:[1]		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 692,012,183 and 651,576,293 shares issued and outstanding at December 31, 2021 and March 31, 2021, respectively	—	—
Additional paid-in capital	4,360,452	3,814,805
Subscription receivable	—	(100,000)
Accumulated deficit	(2,493,662)	(1,918,462)
Accumulated other comprehensive (loss) income	(1,070)	1,445
Shareholders' equity attributable to Roivant Sciences Ltd.	1,865,720	1,797,788
Noncontrolling interests	381,542	241,726
Total shareholders' equity	2,247,262	2,039,514
Total liabilities, redeemable noncontrolling interest and shareholders' equity	$ 2,799,375	$ 2,589,692

[1] Retroactively restated for the stock subdivision as described in Note 3.

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

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share amounts)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Revenue, net	$ 24,341	$ 5,750	$ 46,063	$ 8,649
Operating expenses:				
Cost of revenues	1,384	684	8,507	1,579
Research and development	153,450	202,261	486,335	358,404
General and administrative	115,530	61,875	636,060	178,730
Total operating expenses	270,364	264,820	1,130,902	538,713
Loss from operations	(246,023)	(259,070)	(1,084,839)	(530,064)
Change in fair value of investments	38,036	18,235	14,382	(107,210)
Gain on sale of investment	—	—	(443,754)	—
Change in fair value of debt and liability instruments	23,017	4,304	40,747	31,577
Gain on termination of Sumitomo Options	—	—	(66,472)	—
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	—	—	(115,364)
Other (income) expense, net	(1,029)	(5,788)	2,529	(3,703)
Loss before income taxes	(306,047)	(275,821)	(632,271)	(335,364)
Income tax expense (benefit)	38	(224)	532	1,708
Net loss	(306,085)	(275,597)	(632,803)	(337,072)
Net loss attributable to noncontrolling interests	(21,549)	(14,568)	(57,603)	(37,402)
Net loss attributable to Roivant Sciences Ltd.	$ (284,536)	$ (261,029)	$ (575,200)	$ (299,670)
Net loss per common share—basic and diluted[(1)]	$ (0.41)	$ (0.41)	$ (0.87)	$ (0.48)
Weighted average shares outstanding—basic and diluted[(1)]	686,589,478	629,668,846	662,268,788	629,076,726

(1) Retroactively restated for the stock subdivision as described in Note 3.

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

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited, in thousands)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Net loss	$ (306,085)	$ (275,597)	$ (632,803)	$ (337,072)
Other comprehensive loss:				
Foreign currency translation adjustment	(2,393)	(5,541)	(2,287)	(7,395)
Total other comprehensive loss	(2,393)	(5,541)	(2,287)	(7,395)
Comprehensive loss	(308,478)	(281,138)	(635,090)	(344,467)
Comprehensive loss attributable to noncontrolling interests	(21,591)	(14,303)	(57,375)	(37,069)
Comprehensive loss attributable to Roivant Sciences Ltd.	$ (286,887)	$ (266,835)	$ (577,715)	$ (307,398)

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

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

	Redeemable Noncontrolling Interest	Shareholders' Equity[1]							
		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount						
Balance at March 31, 2021	$ 22,491	651,576,293	$ —	$3,814,805	$ (100,000)	$ 1,445	$(1,918,462)	$ 241,726	$ 2,039,514
Issuance of subsidiary warrants	—	—	—	2,051	—	—	—	24	2,075
Cash contributions to majority-owned subsidiaries	—	—	—	(2,973)	—	—	—	2,973	—
Share-based compensation	—	—	—	11,091	—	—	—	8,178	19,269
Foreign currency translation adjustment	—	—	—	—	—	(2,652)	—	213	(2,439)
Net loss	—	—	—	—	—	—	(82,183)	(18,895)	(101,078)
Balance at June 30, 2021	$ 22,491	651,576,293	$ —	$3,824,974	$ (100,000)	$ (1,207)	$(2,000,645)	$ 234,219	$ 1,957,341
Issuance of the Company's common shares upon closing of Business Combination and PIPE Financing, net of issuance costs	—	32,372,478	—	129,097	—	—	—	—	129,097
Issuance of the Company's common shares related to settlement of transaction consideration	—	840,398	—	—	—	—	—	—	—
Issuance of subsidiary preferred shares	—	—	—	—	—	—	—	70,000	70,000
Issuance of subsidiary common and preferred shares to the Company	—	—	—	(52,189)	—	—	—	52,189	—
Payment of subscription receivable	—	—	—	(40,000)	100,000	—	—	40,000	100,000
Cash contributions to majority-owned subsidiaries	—	—	—	(2,590)	—	—	—	2,590	—
Share-based compensation	—	—	—	386,568	—	—	—	10,744	397,312
Repurchase of equity awards	—	—	—	—	—	—	—	(2,247)	(2,247)
Foreign currency translation adjustment	—	—	—	—	—	2,488	—	57	2,545
Net loss	—	—	—	—	—	—	(208,481)	(17,159)	(225,640)
Balance at September 30, 2021	$ 22,491	684,789,169	$ —	$4,245,860	$ —	$ 1,281	$(2,209,126)	$ 390,393	$ 2,428,408
Issuance of the Company's common shares	—	7,223,014	—	56,116	—	—	—	—	56,116
Cash contributions to majority-owned subsidiaries	—	—	—	(1,175)	—	—	—	1,175	—
Share-based compensation	—	—	—	59,651	—	—	—	11,565	71,216
Foreign currency translation adjustment	—	—	—	—	—	(2,351)	—	(42)	(2,393)
Net loss	—	—	—	—	—	—	(284,536)	(21,549)	(306,085)
Balance at December 31, 2021	$ 22,491	692,012,183	$ —	$4,360,452	$ —	$ (1,070)	$(2,493,662)	$ 381,542	$ 2,247,262

[1] Retroactively restated for the stock subdivision as described in Note 3.

	Redeemable Noncontrolling Interest	Shareholders' Equity[1]							
		Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount						
Balance at March 31, 2020	$ 22,491	628,779,048	$ —	$3,143,739	$ —	$ (2,349)	$(1,109,228)	$ 54,042	$ 2,086,204
Issuance of subsidiary common shares, net of issuance costs	—	—	—	104,581	—	—	—	76,599	181,180
Issuance of subsidiary common shares to the Company	—	—	—	(6,342)	—	—	—	6,342	—
Exercise of subsidiary stock options	—	—	—	36	—	—	—	27	63
Deconsolidation of subsidiary	—	—	—	—	—	—	—	(3,054)	(3,054)
Repurchase of equity awards	—	—	—	(113)	—	—	—	—	(113)
Cash contribution to majority-owned subsidiaries	—	—	—	(149)	—	—	—	149	—
Share-based compensation	—	—	—	9,285	—	—	—	4,993	14,278
Foreign currency translation adjustment	—	—	—	—	—	(854)	—	34	(820)
Net loss	—	—	—	—	—	—	(3,243)	(4,734)	(7,977)
Balance at June 30, 2020	$ 22,491	628,779,048	$ —	$3,251,037	$ —	$ (3,203)	$(1,112,471)	$ 134,398	$ 2,269,761
Issuance of subsidiary common shares, net of issuance costs	—	—	—	101,418	—	—	—	74,499	175,917
Issuance of subsidiary common shares to the Company	—	—	—	(5,318)	—	—	—	5,318	—
Exercise of subsidiary stock options	—	—	—	69	—	—	—	50	119
Consolidation of unconsolidated entity	—	—	—	—	—	—	—	9,178	9,178
Cash contribution to majority-owned subsidiaries	—	—	—	(124)	—	—	—	124	—
Transfer (from) to noncontrolling interest	—	—	—	(255)	—	—	—	255	—
Share-based compensation	—	—	—	8,208	—	—	—	5,706	13,914
Foreign currency translation adjustment	—	—	—	—	—	(1,068)	—	34	(1,034)
Net loss	—	—	—	—	—	—	(35,398)	(18,100)	(53,498)
Balance at September 30, 2020	$ 22,491	628,779,048	$ —	$3,355,035	$ —	$ (4,271)	$(1,147,869)	$ 211,462	$ 2,414,357
Issuance of the Company's common shares	—	1,387,481	—	20,000	—	—	—	—	20,000
Exercise of subsidiary stock options	—	—	—	417	—	—	—	308	725
Transfer (from) to noncontrolling interest	—	—	—	(73)	—	—	—	73	—
Share-based compensation	—	—	—	8,239	—	—	—	9,085	17,324
Foreign currency translation adjustment	—	—	—	—	—	(5,806)	—	265	(5,541)
Net loss	—	—	—	—	—	—	(261,029)	(14,568)	(275,597)
Balance at December 31, 2020	$ 22,491	630,166,529	$ —	$3,383,618	$ —	$ (10,077)	$(1,408,898)	$ 206,625	$ 2,171,268

(1) Retroactively restated for the stock subdivision as described in Note 3.

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

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Nine Months Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (632,803)	$ (337,072)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	78,223	65,175
Share-based compensation	487,797	45,516
Change in fair value of investments	14,382	(107,210)
Gain on sale of investment	(443,754)	—
Change in fair value of debt and liability instruments	40,747	31,577
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	(115,364)
Gain on termination of Sumitomo Options	(61,472)	—
Loss from equity method investment	—	3,750
Other	8,469	2,398
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Accounts payable	3,693	(2,702)
Accrued expenses	35,576	(1,004)
Deferred consideration liability	(50,000)	—
Operating lease liabilities	(6,171)	(3,806)
Other	(4,947)	(27,329)
Net cash used in operating activities	(530,260)	(446,071)
Cash flows from investing activities:		
Cash disposed upon deconsolidation of subsidiary	—	(19,085)
Cash acquired upon consolidation of unconsolidated entity	—	21,439
Investments in unconsolidated entities	—	(28,250)
Proceeds from sale of investment	320,170	—
Purchase of property and equipment	(11,173)	(1,716)
Net cash provided by (used in) investing activities	308,997	(27,612)
Cash flows from financing activities:		
Proceeds from Business Combination and PIPE Financing	213,424	—
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	—	356,756
Proceeds from payment of subscription receivable	100,000	—
Proceeds from subsidiary debt financings, net of financing costs paid	36,400	—
Repayment of long-term debt by subsidiary	(21,590)	—
Payment of offering and loan origination costs	(20,265)	—
Repurchase of equity awards	(2,247)	(113)
Proceeds from exercise of subsidiary stock options	—	907
Net cash provided by financing activities	305,722	357,550
Net change in cash, cash equivalents and restricted cash	84,459	(116,133)
Cash, cash equivalents and restricted cash at beginning of period	2,141,676	2,269,252
Cash, cash equivalents and restricted cash at end of period	$2,226,135	$2,153,119
Non-cash investing and financing activities:		
Operating lease right-of-use assets obtained and exchanged for operating lease liabilities	$ 4,806	$ 1,549
Offering costs included in accounts payable and accrued expenses	$ 31	$ —
Other	$ —	$ (4,351)

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

ROIVANT SCIENCES LTD.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Note 1—Description of Business and Liquidity

(A) Description of Business

Roivant Sciences Ltd. (inclusive of its consolidated subsidiaries, the "Company" or "RSL"), aims to improve health by rapidly delivering innovative medicines and technologies to patients. The Company does this by building biotech and healthcare technology companies ("Vants") and deploying technology to drive greater efficiency in research and development and commercialization. In addition to biopharmaceutical subsidiaries, the Company also builds technology Vants focused on improving the process of developing and commercializing medicines. The Company was founded on April 7, 2014 as a Bermuda exempted limited company.

The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company's subsidiaries are wholly owned subsidiaries and majority-owned or controlled subsidiaries. Refer to Note 4, "Investments" for further discussion of the Company's investments in unconsolidated entities.

On September 30, 2021, RSL completed its business combination with Montes Archimedes Acquisition Corp. ("MAAC"), a special purpose acquisition company, and began trading on Nasdaq under the ticker symbol "ROIV." Refer to Note 3, "Business Combination with MAAC" for additional details.

(B) Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2021, the Company had cash and cash equivalents of approximately $2.2 billion and its accumulated deficit was approximately $2.5 billion. For the nine months ended December 31, 2021 and 2020, the Company incurred net losses of $632.8 million and $337.1 million, respectively. The Company has historically financed its operations primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates or take other steps to conserve capital. The Company expects its existing cash and cash equivalents will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation and Principles of Consolidation

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30, and December 31.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and follow the requirements of the United States Securities and Exchange Commission ("SEC") for interim financial reporting. Accordingly, these unaudited condensed consolidated financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the fiscal year ended March 31, 2021. The unaudited condensed consolidated balance sheet at March 31, 2021 has been derived from the audited consolidated financial statements at that date. In the opinion of management, the unaudited condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the interim periods presented. Certain prior year amounts were reclassified to conform to current year presentation. Operating results for the three and nine months ended December 31, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2022, for any other interim period, or for any other future year.

Any references in these notes to applicable accounting guidance are meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The unaudited condensed consolidated financial statements include the accounts of RSL and the subsidiaries in which it has a controlling financial interest, most often through a majority voting interest. All intercompany balances and transactions have been eliminated in consolidation.

For consolidated entities where the Company owns or is exposed to less than 100% of the economics, the Company records net loss attributable to noncontrolling interests in its unaudited condensed consolidated statements of operations equal to the percentage of common stock ownership interest retained in the respective operations by the noncontrolling parties. The Company presents noncontrolling interests as a component of shareholders’ equity on its unaudited condensed consolidated balance sheets.

The Company accounts for changes in its ownership interest in its subsidiaries while control is retained as equity transactions. The carrying amount of the noncontrolling interest is adjusted to reflect the change in RSL’s ownership interest in the subsidiary. Any difference between the fair value of the consideration received or paid and the amount by which the noncontrolling interest is adjusted is recognized within shareholders’ equity attributable to RSL.

There have been no significant changes in the Company’s accounting policies from those disclosed in the Company’s audited consolidated financial statements for the fiscal year ended March 31, 2021.

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

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses, contingent liabilities, share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of December 31, 2021 and through the issuance of these condensed consolidated financial statements. The Company’s analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

(C) Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights.

(D) Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash and cash equivalents. The Company maintains cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

(E) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Restricted cash classified as a current asset consists of legally restricted non-interest bearing deposit accounts relating to the Company's corporate credit card programs. Restricted cash classified as a long-term asset consists of restricted deposit accounts related to irrevocable standby letters of credit. As of March 31, 2021, restricted cash classified as a current asset included $75.0 million held in escrow for the purpose of fulfilling certain indemnification obligations. The full escrow amount of $75.0 million was disbursed to the Company in June 2021. See Note 6, "Sumitomo Transaction Agreement" for additional information.

Cash as reported in the condensed consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash as presented on the accompanying condensed consolidated balance sheets as follows (in thousands):

	December 31, 2021	March 31, 2021
Cash and cash equivalents	$ 2,214,283	$ 2,055,044
Restricted cash	11,852	86,632
Cash, cash equivalents and restricted cash	$ 2,226,135	$ 2,141,676

(F) Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses any litigation or other claims it may confront to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

(G) Investments

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, "Investments."

(H) Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as R&D. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. R&D costs primarily consist of the intellectual property and R&D materials acquired and expenses from third parties who conduct R&D activities on behalf of the Company.

The Company evaluates in-licensed agreements for in-process research and development projects ("IPR&D") to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as R&D expense in its condensed consolidated statements of operations. The Company initially recognizes contingent consideration in an asset acquisition at fair value. The carrying value of contingent consideration is subsequently adjusted when the contingency is resolved and is paid or becomes payable.

(I) Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include shares of common stock of Arbutus Biopharma Corporation ("Arbutus"); shares of common stock of Sio Gene Therapies Inc. ("Sio"); shares of common stock of Heracles Parent, L.L.C., the parent entity of the Datavant business, (as defined and discussed in Note 4, "Investments"); liability instruments issued, including warrant and earn-out shares liabilities issued in connection with the Company's business combination with MAAC (see Note 3, "Business Combination with MAAC"); the deferred consideration liability; its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus and Sio common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. In October 2021, shares of Arbutus' Series A participating convertible preferred shares ("Arbutus Preferred Shares") held by the Company were converted into shares of common stock of Arbutus pursuant to mandatory conversion provisions. Prior to conversion, the Arbutus Preferred Shares held by the Company were classified as Level 2 as the fair value of such preferred shares was determined based upon the quoted market price of Arbutus common stock into which such preferred shares were convertible. The shares of common stock of Datavant (as defined and discussed in Note 4, "Investments") and liability instruments issued, excluding the Public Warrants (as defined and discussed in Note 3, "Business Combination with MAAC"), are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. The Public Warrants are publicly traded and therefore are classified as Level 1 as the Public Warrants have a readily determinable fair value. Cash, accounts payable, and the deferred consideration liability are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The deferred consideration liability was based on a fixed monetary amount, and payment was based solely on the passage of time. The deferred consideration liability was settled in November 2021 by payment of $50.0 million in cash as well as the issuance of 6,348,057 of the Company's common shares. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant Sciences Ltd. (together with its wholly owned subsidiaries, "Dermavant"), which is stated at amortized cost, approximates fair value based on current interest rates for similar types of borrowings and therefore is included in Level 2 of the fair value hierarchy. Long-term debt issued by Dermavant for which the fair value option has been elected is included in Level 3 of the fair value hierarchy as the assumptions and estimates used in the valuation are unobservable in the market.

(J) Warrant Liabilities

The Company classifies the Roivant Warrants (as defined in Note 3, "Business Combination with MAAC") as liabilities. At the end of each reporting period, changes in fair value during the period are recognized within the condensed consolidated statements of operations. The Company will continue to adjust the carrying value of the liability associated with the Roivant Warrants for changes in the fair value until the earlier of a) the exercise or expiration of the Roivant Warrants or b) the redemption of the Roivant Warrants. Issuance costs incurred that were attributable to the Roivant Warrants were expensed as incurred.

(K) Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU No. 2020-06"). ASU No. 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP. ASU No. 2020-06 also removes certain settlement conditions that are required for equity contracts to qualify for the derivatives scope exception, which will permit more equity contracts to qualify for it. Either a modified retrospective transition method or a fully retrospective transition method is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The early-adoption of ASU No. 2020-06 on April 1, 2021 did not have a material impact on the Company's unaudited condensed consolidated financial statements.

Note 3—Business Combination with MAAC

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

On the Closing Date prior to the effective time of the Merger (the "Effective Time"), RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. The shares, equity awards and net loss per share available to holders of the Company's common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the fixed exchange ratio.

In accordance with the terms of the Business Combination Agreement, at the Effective Time:

a. each share of MAAC Class A common stock (the "MAAC Class A Shares") and each share of MAAC Class B common stock (the "MAAC Class B Shares") that were outstanding immediately before the Effective Time (other than treasury shares and any shares held by Patient Square Capital LLC (the "MAAC Sponsor"), any affiliate of the MAAC Sponsor or any of MAAC's independent directors (the "MAAC Independent Directors") or its transferee) were automatically canceled and extinguished and converted into one common share of RSL (the "Roivant Common Share"),

b. each MAAC Class B Share that was outstanding immediately before the Effective Time and held by the MAAC Sponsor, any affiliate of the MAAC Sponsor or any of the MAAC Independent Directors or its transferee were automatically canceled and extinguished and converted into a number of Roivant Common Shares based on an exchange ratio of 0.75, with a portion of such Roivant Common Shares issued to the MAAC Sponsor, any affiliate of the MAAC Sponsor, any MAAC Independent Director or its transferee by virtue of the Merger being subject to the vesting and other terms and conditions set forth in the Sponsor Support Agreement (as more fully described below),

c. each warrant to purchase MAAC Class A Shares that was outstanding immediately before the Effective Time was converted automatically into a right to acquire a Roivant Common Share (a "Roivant Warrant") at an exercise price of $11.50 per share, subject to certain adjustments.

Following the Merger, the Roivant Common Shares and the Roivant Warrants began trading on the Nasdaq Global Market under the ticker symbols "ROIV" and "ROIVW," respectively, on October 1, 2021.

In connection with the Business Combination, RSL entered into subscription agreements with certain investors, whereby it issued 22,000,000 common shares at $10.00 per share for an aggregate purchase price of $220.0 million (the "PIPE Financing"). The PIPE Financing closed simultaneously with the consummation of the Business Combination.

In connection with the Business Combination and PIPE Financing, the Company received $213.4 million in cash at closing (the "Closing"), net of deferred underwriting expenses and unpaid expenses incurred by MAAC in connection with the transaction. The Company incurred $24.4 million in costs directly related to the Business Combination and PIPE Financing, such as banker fees and costs associated with third-party legal, accounting and other professional services. Upon Closing, these costs, which had been capitalized on the Company's balance sheet were recorded as a reduction of additional paid-in capital with the exception of $7.4 million, which were expensed as they represent the allocation of the transaction costs associated with the warrants and Earn-Out Shares (as defined below) liabilities. Transaction costs were allocated to the warrants and Earn-Out Shares liabilities based on the fair value of such instruments out of the total consideration.

Sponsor Support Agreement

Concurrently with the execution of the Business Combination Agreement, MAAC, the MAAC Sponsor, Roivant and each of the MAAC Independent Directors, entered into the Sponsor Support Agreement, which was subsequently amended on June 9, 2021, to reflect the MAAC Independent Directors and Roivant entering into respective Lock-Up Agreements, and further amended on September 30, 2021.

Pursuant to the Sponsor Support Agreement, among other things:

a. 2,033,591 Roivant Common Shares issued to the MAAC Sponsor and 10,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the "20% Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to $15.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).

b. 1,016,796 Roivant Common Shares issued to the MAAC Sponsor and 5,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the "10% Earn-Out Shares" and, together with the 20% Earn-Out Shares, the "Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to $20.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).

c. The remaining number of Roivant Common Shares issued to the MAAC Sponsor and each MAAC Independent Director are not subject to the vesting conditions described above (the "Retained Shares").

The Vesting Period represents the period commencing on November 9, 2021, the date on which the registration statement on Form S-1 required to be filed by the Company in connection with the PIPE Financing was declared effective, and ending no later than the fifth anniversary of the Closing (the "Vesting Period"). The Vesting Period will, if a definitive purchase agreement with respect to a Sale (as defined in the Sponsor Support Agreement) is entered into on or prior to the end of such period, be extended to the earlier of one day after the consummation of such Sale and the termination of such definitive transaction agreement, and if a Sale occurs during such Vesting Period, then all of the Earn-Out Shares unvested as of such time will automatically vest immediately prior to the consummation of such Sale. If any Earn-Out Shares have not vested on or prior to the end of such Vesting Period, then such Earn-Out Shares will be forfeited.

The Earn-Out Shares require liability classification requirements and are classified as "Liability instruments measured at fair value" on the condensed consolidated balance sheets. The Earn-Out Shares liability is subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company's statement of operations.

Lock-Up Agreements

On May 1, 2021 and June 9, 2021, RSL, on the one hand, and the MAAC Sponsor, the MAAC Independent Directors and certain Roivant equityholders, on the other hand, entered into lock-up agreements, pursuant to which, among other things, the MAAC Sponsor, the MAAC Independent Directors and such Roivant equityholders have agreed not to effect any sale or distribution of the Roivant Common Shares (including those underlying incentive equity awards or Roivant Warrants) held by the MAAC Sponsor, the MAAC Independent Directors or such equityholders as of immediately following the Closing during the applicable lock-up period, subject to customary exceptions.

The lock-up period applicable to Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors as of immediately following the Closing will be (i) with respect to 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, six months following the Closing, (ii) with respect to an additional 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, the earlier of twelve months following the achievement of certain price-based vesting restrictions or six years from the Closing and (iii) with respect to 50% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, thirty-six months following the Closing.

The Roivant Common Shares underlying warrants held by the MAAC Sponsor as of immediately following the Closing will be subject to a corresponding lock-up period for (a) with respect to 25% of such warrants held by the MAAC Sponsor, six months from the Closing, (b) with respect to an additional 25% of such warrants held by the MAAC Sponsor, twelve months from Closing and (c) with respect to 50% of such warrants held by the MAAC Sponsor, thirty-six months from the Closing.

The lock-up period applicable to Roivant Common Shares held by certain Roivant equityholders as of immediately following the Closing (including those underlying incentive equity awards) will be (x) with respect to 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), six months following the Closing, (y) with respect to an additional 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), twelve months following the Closing and (z) with respect to 50% of the Roivant Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, thirty-six months following the Closing.

Common Stock Warrants

At the effective time of the Merger, 10,214,365 Roivant Warrants that were held by the MAAC Sponsor at an exercise price of $11.50 (the "Private Placement Warrants") and 20,535,896 Roivant Warrants held by MAAC's shareholders at an exercise price of $11.50 (the "Public Warrants") were converted into the right to acquire Roivant Common Shares. Pursuant to the agreement governing the Roivant Warrants, the Roivant Warrants became exercisable 30 days following the completion of the Business Combination. The Roivant Warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

The Private Placement Warrants are generally identical to the Public Warrants, except that (i) the Private Placement Warrants (including the common stock issuable upon exercise of the Private Placement Warrants) were not transferable, assignable or salable until 30 days after the completion of the Business Combination (ii) they will not be redeemable by the Company when the price per share of Roivant Common Shares equals or exceeds $18.00, and (iii) the Private Placement Warrants may be exercised by holders on a cashless basis. If the Private Placement Warrants are held by holders other than our sponsor or its permitted transferees, the Private Placement Warrants will be redeemable by Roivant in all redemption scenarios and exercisable by the holders on the same basis as the Public Warrants.

The Roivant Warrants require liability classification requirements and are classified as "Liability instruments measured at fair value" on the condensed consolidated balance sheets. The Private Placement Warrants liability and Public Warrants liability are subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company's statement of operations.

Redemption of Roivant Warrants when the price per share of Roivant Common Shares equals or exceeds $18.00.

The Company may redeem the outstanding Roivant Warrants for cash (except with respect to the Private Placement Warrants):

- in whole and not in part;
- at a price of $0.01 per Roivant Warrant;
- upon a minimum of 30 days' prior written notice of redemption; and
- if, and only if, the last reported sale price of common stock for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends the notice of redemption to the warrantholders (the "Reference Value") equals or exceeds $18.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like).

However, in this case, the Company will not redeem the Roivant Warrants unless an effective registration statement under the Securities Act covering the Roivant Common Shares issuable upon exercise of the Roivant Warrants is effective and a current prospectus relating to those Roivant Common Shares is available throughout the 30-day redemption period. Any such exercise would not be on a "cashless" basis and would require the exercising warrantholder to pay the exercise price for each Roivant Warrant being exercised.

Redemption of Roivant Warrants when the price per share of Roivant Common Shares equals or exceeds $10.00.

The Company may redeem the outstanding Roivant Warrants (except as described herein with respect to the Private Placement Warrants):

- in whole and not in part;
- at $0.10 per Roivant Warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their Roivant Warrants on a cashless basis prior to redemption and receive that number of Roivant Common Shares determined by reference to an agreed table based on the redemption date and the "fair market value" of the Roivant Common Shares; and
- if, and only if, the Reference Value equals or exceeds $10.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like); and
- if the Reference Value is less than $18.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like), the Private Placement Warrants must also concurrently be called for redemption on the same terms (except as described herein with respect to a holder's ability to cashless exercise its warrants) as the outstanding Public Warrants, as described above.

For these purposes, "fair market value" of Roivant Common Shares shall mean the volume-weighted average price of common stock for the 10 trading days immediately following the date on which the notice of redemption is sent to warrantholders. In no event will the Roivant Warrants be exercisable in connection with this redemption feature for more than 0.361 Roivant Common Shares per Roivant Warrant (subject to adjustment).

Note 4—Investments

Investment in Arbutus

RSL owns 38,847,462 shares of common stock of Arbutus, following the mandatory conversion of 1,164,000 Arbutus Preferred Shares held by RSL into 22,833,922 shares of Arbutus common stock in October 2021 in accordance with the terms of the subscription agreement entered into by RSL and Arbutus in October 2017. The Company accounts for its investment in Arbutus as an equity method investment accounted for using the fair value option. Due to the Company's significant influence over operating and financial policies, Arbutus is considered a related party of the Company. At December 31, 2021, RSL held approximately 27% of issued and outstanding shares of Arbutus.

At December 31, 2021 and March 31, 2021, the aggregate fair value of the RSL investment in Arbutus was $151.1 million and $129.4 million, respectively. During the three and nine months ended December 31, 2021, the Company recognized an unrealized loss of $15.6 million and unrealized gain of $21.7 million, respectively, on its investments in Arbutus in the accompanying condensed consolidated statements of operations. During the three and nine months ended December 31, 2020, the Company recognized unrealized gains on its investments in Arbutus of $16.3 million and $98.7 million, respectively, in the accompanying condensed consolidated statements of operations. The fair value of the Company's investment was determined using the closing price of Arbutus's common stock on December 31, 2021 and March 31, 2021 of $3.89 and $3.33, respectively.

Investment in Sio

Following the completion of Sio's underwritten public offering in February 2020, RSL's ownership interest fell below 50.0%. As such, the Company no longer has a controlling financial interest in Sio. Accordingly, the Company deconsolidated Sio in February 2020. Due to the Company's significant influence over operating and financial policies, Sio remains a related party of the Company following deconsolidation. As the Company still has the ability to exercise significant influence over the operating and financial policies of Sio, the Company has determined that its retained interest represents an equity method investment after the date of deconsolidation. Upon deconsolidation, the retained interest was recorded at fair market value based on the closing price of Sio's common stock. The fair value option was elected to continuously remeasure the investment to fair value each reporting period after the initial measurement. At December 31, 2021, RSL held approximately 25% of Sio's issued and outstanding common shares.

At December 31, 2021 and March 31, 2021, the fair value of the Company's investment in Sio was $24.0 million and $48.5 million, respectively. During the three and nine months ended December 31, 2021, the Company recognized unrealized losses on its investment in Sio of $16.3 million and $24.5 million, respectively, in the accompanying condensed consolidated statements of operations. During the three and nine months ended December 31, 2020, the Company recognized an unrealized loss of $34.2 million and an unrealized gain of $6.3 million, respectively, on its investment in Sio in the accompanying condensed consolidated statements of operations. The fair value of common shares held by the Company was determined using the closing price of Sio's common stock on December 31, 2021 and March 31, 2021 of $1.29 and $2.61, respectively.

Investment in Datavant

In April 2020, Datavant Holdings, Inc. ("Datavant") completed an initial round of a Series B equity raise by which 13,411,311 Series B preferred shares were issued in April 2020 for gross proceeds of $27.2 million, including 1,065,234 Series B preferred shares issued and sold to RSL for a total purchase price of $2.5 million and 1,800,253 Series B shares issued relating to the conversion of certain liability instruments. As a result of this transaction, along with a restructuring of Datavant's equity classes, RSL no longer controls Datavant. As such, the Company deconsolidated Datavant as of April 2020. Due to the Company's significant influence over operating and financial policies, Datavant remains a related party of the Company following deconsolidation. Upon deconsolidation, the Company recorded its investment in Datavant based on the fair value of Datavant preferred shares held of $99.0 million. Prior to the Datavant Merger (defined below), the Company accounted for its investment in Datavant using the measurement alternative to fair value. Under the measurement alternative, the investment is remeasured upon observable price changes in orderly transactions or upon impairment, if any. The Company recognized a gain on deconsolidation of $86.5 million in the accompanying condensed consolidated statements of operations for the nine months ended December 31, 2020. In July 2020, Datavant issued and sold 639,140 Series B preferred shares to RSL at a price consistent with that of the initial round of Datavant's Series B equity raise, which resulted in an increase in the carrying value of the Company's investment to $100.6 million.

In June 2021, Datavant and Heracles Parent, L.L.C. (referred to herein as "Ciox Parent" and, after the closing of the Datavant Merger (as defined below), "Datavant"), a provider of healthcare information services and technology solutions to hospitals, health systems, physician practices and authorized recipients of protected health records in the United States, primarily through its wholly owned subsidiary CIOX Health, LLC, entered into a definitive agreement to merge Datavant with and into a newly formed wholly owned subsidiary of Ciox Parent (the "Datavant Merger"). The merger closed on July 27, 2021. At closing, the Company received approximately $320 million in cash and a minority equity stake representing approximately 17% of the outstanding Class A units in Ciox Parent. Ciox Parent's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted. As a result of the transaction, the Company recognized a gain on remeasurement of $443.8 million in the accompanying condensed consolidated statements of operations for the nine months ended December 31, 2021.

Following the completion of the Datavant Merger, the Company's minority equity interest became subject to the equity method of accounting. At such time, the fair value option was elected to continuously remeasure the investment to fair value each reporting period with changes in fair value reflected in earnings. As of December 31, 2021 and July 27, 2021, the fair value of the Company's investment was $215.7 million and $224.1 million, respectively, with the Company recognizing unrealized losses on its investment of $4.3 million and $8.4 million, respectively, for the three and nine months ended December 31, 2021. The fair value of the Company's investment was determined using valuation models that incorporate significant unobservable inputs and is classified as a Level 3 measurement within the fair value hierarchy. Refer to Note 13, "Fair Value Measurements" for more information.

Other Investment

The Company holds an additional equity investment that is measured using the fair value option. The fair value of this investment was $7.9 million and $11.1 million as of December 31, 2021 and March 31, 2021, respectively.

Note 5—Asset Acquisitions and License Agreements

Priovant

In September 2021, Priovant, Inc. ("Priovant") in-licensed certain intellectual property rights. The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The fair value of consideration transferred was $82.1 million, consisting of $70.0 million of preferred stock representing a dilution-protected minority ownership interest in Priovant; a $10.0 million upfront cash payment; and $2.1 million relating to other obligations. The acquired rights, which included the licensed rights, starting materials and in-process inventory for each drug candidate, represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded $82.1 million as research and development expense in the accompanying condensed consolidated statements of operations for the nine months ended December 31, 2021.

Additionally, Priovant agreed to pay a future sales-based milestone payment and tiered royalties based on sales in the US and certain specified territories.

Hemavant

In November 2021, Pharmavant 7 GmbH ("Hemavant"), a wholly owned subsidiary of the Company, entered into a license agreement with Eisai Co., Ltd. ("Eisai") (the "Eisai License Agreement"). Pursuant to the Eisai License Agreement, Eisai granted Hemavant (i) an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and know-how and (ii) a non-exclusive, worldwide, sublicensable, royalty-bearing license under certain additional patents, know-how and inventions, in each case, to develop, manufacture and commercialize the compound known as RVT-2001 and products incorporating RVT-2001 for all human and animal uses. In exchange for the rights, the Company made an upfront payment to Eisai consisting of $8.0 million in cash and the issuance of $7.0 million in shares of the Company's common stock at an agreed price of $8.00 per share. Hemavant may also be obligated to pay up to a maximum of $65.0 million in development and regulatory milestone payments (with respect the product for the first indication) and up to a maximum of $18.0 million in payments (with respect to the product for each additional indication) and up to a maximum of $295.0 million in commercial milestone payments. Hemavant may also be obligated to pay a tiered high single-digit to sub-teens royalty, subject to certain customary reductions, on net sales of licensed products.

The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The acquired rights, which include the licensed rights and in-process inventory of the drug candidate, represent in-process research and development assets that were determined to have no alternative future use. The fair value of the 874,957 shares of the Company's common stock issued to Eisai based on the closing price as of the effective date of the Eisai License Agreement was $6.1 million. Accordingly, the Company recorded $14.1 million as research and development expense in the accompanying condensed consolidated statements of operations for the three and nine months ended December 31, 2021.

Note 6—Sumitomo Transaction Agreement

On December 27, 2019 (the "Sumitomo Closing Date"), RSL and Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") completed the transactions contemplated by the transaction agreement by and between RSL and Sumitomo, dated as of October 31, 2019 (the "Sumitomo Transaction Agreement"). Pursuant to the Sumitomo Transaction Agreement, RSL transferred its entire ownership interest in Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd. and Spirovant Sciences Ltd. (collectively, the "Sumitovant Vants") to a newly formed, wholly-owned entity ("Sumitovant").

RSL's ownership interest in Sumitovant was then transferred to Sumitomo, such that following the Sumitomo Closing Date, Sumitovant and its subsidiaries, including the Sumitovant Vants, were each directly or indirectly owned by Sumitomo. Additionally, in connection with the Sumitomo Transaction Agreement, RSL (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of RSL's ownership interests in six other subsidiaries (Dermavant, Genevant Sciences Ltd. ("Genevant"), Lysovant Sciences Ltd., Metavant Sciences Ltd., Roivant Asia Cell Therapy Holdings Ltd., and Sinovant Sciences HK Limited (collectively, the "Option Vants")), (ii) (a) transferred the proprietary technology platform DrugOme to Sumitomo (for which RSL retains a perpetual royalty free license for internal use) and (b) licensed the Digital Innovation technology platform to Sumitomo (for which both parties retain ongoing access), and (iii) transferred 78,867,360 common shares of RSL to Sumitomo. On the Sumitomo Closing Date, the Company received approximately $2.9 billion in cash. Additionally, $75.0 million was deposited into a segregated escrow account for the purpose of fulfilling indemnification obligations of RSL that may become due to Sumitomo. The full escrow amount of $75.0 million was disbursed to the Company in June 2021. In connection with the Sumitomo Transaction, RSL's board of directors approved an exchange and offer to repurchase RSL equity securities for up to $1.0 billion of the proceeds received from Sumitomo.

Concurrently with the Sumitomo Transaction Agreement, (i) RSL, Sumitomo and Sumitovant entered into a transition services agreement, whereby each of the parties thereto agreed to provide certain services to one another at cost for a period of time following the Sumitomo Closing Date and (ii) RSL and Sumitomo entered into a strategic cooperation agreement relating to certain ongoing technology-related collaborations between the parties. Pursuant to the terms of the transition services agreement and strategic cooperation agreement, RSL billed Sumitovant $0.2 million and $0.8 million, net of amounts billed by Sumitovant to RSL, during the three and nine months ended December 31, 2021, respectively. During the three and nine months ended December 31, 2020, RSL billed Sumitovant $0.3 million and $1.1 million, net of amounts billed by Sumitovant to RSL, respectively, for costs incurred on behalf of Sumitovant, which were recorded as an offsets to the general and administrative expenses initially charged. The period for certain services provided under the Transition Services Agreement expired in December 2020.

In conjunction with the Sumitomo Transaction, certain employees of the Company became employees of Sumitovant or its subsidiaries. The Company issued certain instruments to these employees that vest based on the achievement of time-based, performance or liquidity event requirements. As of December 31, 2021 and 2020, there were 5,134,088 and 5,470,387 outstanding instruments, respectively, held by Sumitovant employees for which aggregate fair value was recorded against the gain on sale of business.

In May 2021, the Company entered into an Asset Purchase Agreement with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. ("SPC") (the "Asset Purchase Agreement"). The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire the Company's equity interests in the Option Vants (the "Sumitomo Options"); (ii) the Company transferred and assigned to SPC all of its intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively "Greater China"), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) Sumitomo agreed to pay the Company $5.0 million in cash; and (iv) Sumitomo entered into an agreement with the Company to pursue future collaborations with Genevant. The Company received the cash payment, net of certain withholding taxes, in August 2021. The Company recorded a gain on the termination of the Sumitomo Options of $66.5 million, consisting of the fair value of the Sumitomo Options on the date of termination and the expected cash payment, in the accompanying condensed consolidated statements of operations for the nine months ended December 31, 2021.

Note 7—Certain Balance Sheet Components

(A) Other Current Assets

Other current assets at December 31, 2021 and March 31, 2021 consisted of the following (in thousands):

	December 31, 2021	March 31, 2021
Prepaid expenses	$ 50,952	$ 39,544
Trade and other receivables, net	8,921	11,222
Income tax receivable	2,627	1,803
Other	7,834	1,681
Total other current assets	$ 70,334	$ 54,250

(B) Accrued Expenses

Accrued expenses at December 31, 2021 and March 31, 2021 consisted of the following (in thousands):

	December 31, 2021	March 31, 2021
Research and development expenses	$ 67,796	$ 20,755
Compensation-related expenses	31,115	38,552
Professional services expenses	5,411	10,267
Other general and administrative expenses	8,357	7,362
Total accrued expenses	$ 112,679	$ 76,936

(C) Other Current Liabilities

Other current liabilities at December 31, 2021 and March 31, 2021 consisted of the following (in thousands):

	December 31, 2021	March 31, 2021
Deferred revenue	$ 4,972	$ 5,918
Income tax payable	813	207
Other	6,650	3,037
Total other current liabilities	$ 12,435	$ 9,162

Note 8—Long-Term Debt and Loan Commitment

(A) Long-Term Debt

Long-term debt, net consists of the following (in thousands):

	December 31, 2021	March 31, 2021
Principal amount	$ 211,900	$ 170,100
Exit fee / end of term charge	5,000	1,390
Less: unamortized debt discount and issuance costs	(12,858)	(1,210)
Total debt, net	204,042	170,280
Less: current portion	—	—
Total long-term debt, net	$ 204,042	$ 170,280

Dermavant

In May 2019, Dermavant entered into a loan and security agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules"), pursuant to which Dermavant borrowed an aggregate of $20.0 million, which bore interest at a variable per annum rate at the greater of (i) 9.95% or (ii) the prime rate plus 4.45%. Dermavant was also obligated to pay an end of term charge of $1.4 million. Following the achievement of certain milestones, the term loan maturity was extended to June 1, 2023 with interest-only monthly payments through December 2021. All amounts outstanding under the Hercules Loan Agreement were repaid in May 2021 using the proceeds from a $40.0 million senior secured credit facility (the "Credit Facility") entered into by Dermavant and certain of its subsidiaries in May 2021 with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent. The Credit Facility has a five-year maturity and bears an interest rate of 10.0% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter through the maturity date. A lump sum principal payment is due on the maturity date. Dermavant is also obligated to pay an exit fee of $5.0 million. The exit fee can be reduced to $4.0 million upon achievement of certain equity milestones defined in the agreement, which are not deemed likely as of December 31, 2021. In connection with the funding of the Credit Facility, Dermavant issued a warrant to XYQ Luxco to purchase 1,199,072 common shares of Dermavant at an exercise price of $0.01 per common share.

In connection with Dermavant's acquisition of tapinarof from GlaxoSmithKline Intellectual Property Development Ltd. and Glaxo Group Limited (collectively "GSK") pursuant to an asset purchase agreement (the "GSK Agreement"), Dermavant and NovaQuest Co-Investment Fund VIII, L.P. ("NovaQuest") entered into a funding agreement (the "NovaQuest Agreement"). Pursuant to the NovaQuest Agreement, Dermavant borrowed $100.0 million in August 2018 and $17.5 million in October 2018 in exchange for an obligation to make certain variable future payments calculated as a function of the achievement of regulatory and commercial milestones or events of termination. The aggregate maximum amount of regulatory milestone payments that Dermavant could be required to make under the NovaQuest Agreement is $440.6 million, and the maximum aggregate amount of commercial milestone payments is $141.0 million. In some circumstances, Dermavant may be able to offset certain of the regulatory milestone payments with up to $88.1 million of the commercial milestone payments. At issuance, the Company concluded that certain features of the long-term debt would be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, the Company has elected the fair value option for this financial instrument and will record the changes in the fair value within the statements of operations at the end of each reporting period. Direct costs and fees related to the debt issued under the NovaQuest Agreement were recognized in earnings. As of December 31, 2021 and March 31, 2021, the fair value of the debt was $171.9 million and $150.1 million, respectively. Refer to Note 13, "Fair Value Measurements" for additional details regarding the fair value measurement.

(B) Loan Commitment

In May 2021, Dermavant, as seller, entered into a $160.0 million revenue interest purchase and sale agreement (the "RIPSA") for its investigational product tapinarof with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P. (collectively, the "Purchasers"), together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, the Purchasers procured a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States in exchange for $160.0 million in committed funding to be paid to Dermavant, conditional based on the approval of tapinarof by the FDA. The agreement will be canceled if funding has not occurred by July 2023. Dermavant acquired the worldwide rights to tapinarof (other than with respect to certain rights in China) in August 2018 pursuant to the GSK Agreement. Dermavant intends to use the RIPSA proceeds for the payment of certain one-time milestone obligations that become payable upon the approval and commercialization of tapinarof for the treatment of psoriasis in the United States as well as for other general corporate purposes.

Note 9—Shareholders' Equity and Redeemable Noncontrolling Interest

(A) RSL Common Stock

In connection with the closing of the Business Combination, the Company adjusted its authorized share capital to equal 7,000,000,000 Roivant Common Shares, par value $0.0000000341740141 per share. Each Roivant Common Share has the right to one vote. The holders of Roivant Common Shares are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the board of directors since the Company's inception.

On September 30, 2021 in connection with the closing of the Business Combination, RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. All per share amounts and number of shares in the condensed consolidated financial statements and related notes have been retroactively restated to reflect the stock split.

(B) Consolidated Vant Equity Transaction

Proteovant

In July 2021, Proteovant Sciences, Inc. ("Proteovant") collected the subscription receivable relating to the second $100.0 million payment due under a subscription agreement entered into with SK, Inc. ("SK") in December 2020 pursuant to which SK agreed to make a $200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date.

Note 10—Share-Based Compensation

(A) Share-Based Compensation Expense

Share-based compensation expense during the three and nine months ended December 31, 2021 and 2020 was as follows (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Share-based compensation expense recognized as:				
Research and development expenses	$17,669	$ 3,754	$ 47,441	$ 6,760
General and administrative expenses	53,547	13,570	440,356	38,756
Total	$71,216	$17,324	$487,797	$45,516

The achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination resulted in the recognition of a one-time catch-up expense of $372.9 million in September 2021 relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. This one-time catch-up expense is reflected in the accompanying condensed consolidated statements of operations for the nine months ended December 31, 2021.

(B) RSL Equity Incentive Plans

RSL has three equity incentives 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. As of December 31, 2021, there were approximately 60,709,875 common shares available for future grants under the RSL 2021 EIP.

(C) Stock Options and Performance Stock Options

Activity for stock options and performance options under the RSL Equity Plans for the nine months ended December 31, 2021 is as follows:

	Number of Options
Options outstanding at March 31, 2021	69,687,308
Granted	11,999,734
Forfeited	(932,868)
Options outstanding at December 31, 2021	80,754,174

(D) Restricted Stock Units and Performance Stock Units

Activity for restricted stock units and performance stock units under the RSL Equity Plans for the nine months ended December 31, 2021 is as follows:

	Number of Shares
Non-vested balance at March 31, 2021	7,294,028
Granted	19,757,518
Vested	(3,448,650)
Forfeited	(1,015,215)
Non-vested balance at December 31, 2021	22,587,681

Restricted stock units that have vested as of closing of the Business Combination and at any time prior to the expiration of the lockup are expected to be settled on the first business day immediately following expiration of the lock-up period (but in no event later than June 15, 2022). The lock-up is expected to expire on or about March 30, 2022.

(E) Capped Value Appreciation Rights

March 2020 CVAR Grants

In March 2020, the Company granted capped value appreciation rights ("CVARs") that will 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. As of December 31, 2021, there are 16,223,818 non-vested CVARs and 16,223,808 vested CVARs relating to the March 2020 grants. CVARs that have vested as of closing of the Business Combination and at any time prior to the expiration of the lockup are expected to be settled on the first business day immediately following expiration of the lock-up period (but in no event later than June 15, 2022). The lock-up is expected to expire on or about March 30, 2022.

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 will 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. The grant date fair value of the CVARs granted in November 2021 is $31.3 million, which will be recognized over the requisite service period.

(F) Subsidiary Equity Incentive Plans

Certain wholly owned and majority-owned or controlled subsidiaries of RSL adopt their own equity incentive plan ("EIP"). Each EIP is generally structured so that the applicable subsidiary, and its affiliates' employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted stock unit awards, and other share awards under their respective EIP. The Company recorded share-based compensation expense of $12.9 million and $32.4 million for the three and nine months ended December 31, 2021, respectively, and $9.0 million and $21.4 million for the three and nine months ended December 31, 2020, respectively, related to subsidiary EIPs.

Note 11—Income Taxes

The Company's effective tax rate for the three and nine months ended December 31, 2021 was (0.01)% and (0.1)%, respectively, and the effective tax rate for three and nine months ended December 31, 2020 was 0.1% and (0.5)%, respectively. The effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of its deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary.

Note 12—Commitments and Contingencies

(A) Significant Agreements

The Company, primarily through its subsidiaries, has entered into commitments under various asset acquisition and license agreements. Additionally, the Company, through its subsidiaries, enters into agreements with contract service providers to assist in the performance of its R&D activities. Expenditures to contract research organizations and contract manufacturing organizations represent significant costs in the clinical development of its product candidates. Subject to required notice periods and certain obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(B) Loss Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated, and if the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation or claim, including an estimable range, if possible. The Company is currently not involved in any legal proceedings with a probable and estimable material loss.

(C) Intellectual Property Agreements

As of December 31, 2021, the Company did not have any ongoing material financial commitments, other than pursuant to various asset acquisition and license agreements.

(D) COVID-19 Pandemic

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

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

(E) Litigation

As the Company's subsidiary, Immunovant, Inc. ("Immunovant"), has previously disclosed, in February 2021, a putative securities class action complaint was filed against Immunovant, and certain of its current and former officers in the U.S. District Court for the Eastern District of New York on behalf of a class consisting of those who acquired Immunovant's securities from October 2, 2019 and February 1, 2021. The complaint alleged that Immunovant and certain of its officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and misleading statements regarding the safety of batoclimab and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. On December 29, 2021, the U.S. District Court appointed a lead plaintiff. On February 1, 2022, the lead plaintiff filed an amended complaint adding both (i) the Company and (ii) Immunovant's directors and underwriters as defendants, and asserting additional claims under Section 11, 12(a)(2), and 15 of the Securities Act of 1933. Pending court approval of the parties' stipulation, defendants are not required to respond to this amended complaint. The deadline for lead plaintiff to file the operative amended complaint is March 15, 2022. The Company expects defendants, including the Company, to file a motion to dismiss that amended complaint. The Company intends to vigorously defend the case and has not recorded a liability related to this lawsuit because, at this time, the Company is unable to reasonably estimate possible losses or determine whether an unfavorable outcome is either probable or remote.

Note 13—Fair Value Measurements

Recurring Fair Value Measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2021 and March 31, 2021, by level, within the fair value hierarchy (in thousands):

	As of December 31, 2021				As of March 31, 2021			
	Level 1	Level 2	Level 3	Balance as of December 31, 2021	Level 1	Level 2	Level 3	Balance as of March 31, 2021
Assets:								
Money market funds	$1,448,771	$ —	$ —	$1,448,771	$1,420,597	$ —	$ —	$1,420,597
Investment in Datavant Class A units	—	—	215,681	215,681	—	—	—	—
Investment in Sio common shares	23,965	—	—	23,965	48,487	—	—	48,487
Investment in Arbutus common shares	151,116	—	—	151,116	53,325	—	—	53,325
Investment in Arbutus convertible preferred shares	—	—	—	—	—	76,037	—	76,037
Other investment	7,981	—	—	7,981	11,129	—	—	11,129
Total assets at fair value	$1,631,833	$ —	$215,681	$1,847,514	$1,533,538	$76,037	$ —	$1,609,575
Liabilities:								
Debt issued by Dermavant to NovaQuest	$ —	$ —	$171,900	$ 171,900	$ —	$ —	$150,100	$ 150,100
Liability instruments measured at fair value[(1)]	42,098	—	52,502	94,600	—	—	67,893	67,893
Total liabilities at fair value	$ 42,098	$ —	$224,402	$ 266,500	$ —	$ —	$217,993	$ 217,993

(1) At December 31, 2021, Level 1 includes the fair value of the Public Warrants of $42.1 million, and Level 3 includes the fair value of the Earn-Out Shares of $23.1 million, Private Placement Warrants of $21.0, and other liability instruments issued of $8.4 million. At March 31, 2021, Level 3 includes the fair value of the Sumitomo Options of $62.4 million and other liability instrument issued of $5.5 million.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the nine months ended December 31, 2021.

Level 3 Disclosures

The Company measures its Level 3 assets and liabilities at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the Level 3 assets and liabilities uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value related to updated assumptions and estimates are recorded within the statements of operations at the end of each reporting period.

The fair value of Level 3 assets and liabilities may change significantly as additional data are obtained, impacting the Company's assumptions regarding probabilities of potential scenarios used to estimate fair value. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The changes in fair value of the Level 3 assets during the nine months ended December 31, 2021 were as follows (in thousands):

Balance at March 31, 2021	$ —
Fair value of investment in Datavant at recognition date	224,147
Changes in fair value of investment in Datavant, included in net loss	(8,466)
Balance at December 31, 2021	$215,681

There were no Level 3 assets held during the nine months ended December 31, 2020.

The changes in fair value of the Level 3 liabilities during the nine months ended December 31, 2021 and 2020 were as follows (in thousands):

Balance at March 31, 2020	$191,473
Changes in fair value of debt and liability instruments, included in net loss	31,577
Liability instruments disposed due to deconsolidation of subsidiary	(3,325)
Balance at December 31, 2020	$219,725
Balance at March 31, 2021	$217,993
Fair value of liability instrument issued	38,634
Changes in fair value of debt and liability instruments, included in net loss	29,247
Termination of DSP Options	(61,472)
Balance at December 31, 2021	$224,402

Investment in Datavant

The Company elected the fair value option to account for the investment in Datavant. The estimate of fair value for this investment was determined using an option pricing 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 December 31, 2021
Volatility	100.0%
Risk-free rate	0.41%

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of December 31, 2021 and March 31, 2021 represents the fair value of amounts payable to NovaQuest using the Monte Carlo simulation method under the income approach determined by using probability assessments of the expected future payments through 2032 and applying discount rates ranging from 10% to 12%. The future payments are based on significant inputs that are not observable in the market which are subject to remeasurement at each reporting date. The estimates of fair value may not be indicative of the amounts that could ultimately be paid by Dermavant to NovaQuest.

Earn-Out Shares

The fair value of the Earn-Out Shares issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to include the lock-up periods to which the Earn-Out Shares are subject. Refer to Note 3, "Business Combination with MAAC" for additional details. Significant unobservable inputs used to calculate the fair value of the Earn-Out Shares included the following:

Input	Point Estimate Used As of December 31, 2021
Volatility	80.6%
Risk-free rate	1.22%

As of December 31, 2021, the fair value of the Earn-Out Shares was $23.1 million. Earn-Out Shares are included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Private Placement Warrants

The fair value of the Private Placement Warrants issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to incorporate the redemption features as discussed in Note 3, "Business Combination" and the added restriction by which the Company cannot redeem the Private Warrants if the Reference Value is greater than $18.00. Significant unobservable inputs used to calculate the fair value of the Private Placement Warrants included the following:

Input	Point Estimate Used As of December 31, 2021
Volatility	32.5%
Risk-free rate	1.22%
Term (in years)	4.75

As of December 31, 2021, the fair value of the Private Placement Warrants was $21.0 million. The Private Placement Warrants are included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Note 14—Other (Income) Expense, Net

Other (income) expense, net was as follows (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	2020	2021	2020
Loss from equity method investment	$ —	$ —	$ —	$ 3,750
Interest income	(66)	(159)	(199)	(1,359)
Interest expense	1,501	737	5,566	2,136
Other income	(2,464)	(6,366)	(2,838)	(8,230)
Total	$ (1,029)	$ (5,788)	$ 2,529	$ (3,703)

Note 15—Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss attributable to Roivant Sciences Ltd. by the weighted-average number of common stock outstanding during the period. Diluted net loss per common share is computed by dividing the net loss attributable to Roivant Sciences Ltd. by the diluted weighted-average number of common stock outstanding during the period.

For periods of loss, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common share equivalents is anti-dilutive. All outstanding common stock equivalents have been excluded from the computation of diluted loss per share because their effect was anti-dilutive due to the net loss.

As of December 31, 2021 and 2020, potentially dilutive securities were as follows:

	December 31, 2021	December 31, 2020
Stock options and performance stock options	80,754,174	69,852,354
Restricted stock units and performance stock units (non-vested)(1)	22,587,681	6,458,269
March 2020 CVARs(2)	32,447,626	32,447,626
November 2021 CVARs	6,317,350	—
Restricted common stock (non-vested)	988,540	—
Earn-Out Shares (non-vested)	3,080,387	—
Private Placement Warrants	10,214,365	—
Public Warrants	20,535,896	—
Other instruments issued	5,134,088	5,470,387

(1) Vested restricted stock units were treated as outstanding common shares for purposes of calculating net loss per common share for the three and nine months ended December 31, 2021.

(2) Refer to Note 10, "Share-Based Compensation" for details regarding settlement of CVARs. Vested CVARs will be settled on the first business day immediately following expiration of the lock-up period.

Note 16—Subsequent Events

On February 14, 2022, the Company entered into a committed equity facility (the "Facility") with an affiliate of Cantor Fitzgerald & Co. ("Cantor"). Under the terms of the Facility, Cantor has committed to purchase up to an aggregate of $250.0 million in the Company's common shares from time to time at the request of the Company, subject to certain limitations and the satisfaction of certain conditions. Any sales of the Company's common shares to Cantor under the Facility will be made at 99% of the volume-weighted average price of the Company's common shares on Nasdaq on a given trading day. In consideration for entry into the Facility, the Company agreed to pay Cantor an upfront commitment fee in the form of 145,986 common shares.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of Roivant's financial condition and results of operations should be read in conjunction with Roivant's (1) unaudited condensed consolidated financial statements and notes to those statements included in this Quarterly Report on Form 10-Q ("Quarterly Report") and (2) audited consolidated financial statements and notes to those statements and management's discussion and analysis of financial condition and results of operations for the fiscal year ended March 31, 2021, included in our proxy statement/prospectus filed with the SEC on August 10, 2021 (the "Proxy Statement / Prospectus"). Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Roivant's actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. Please see "Cautionary Statement Regarding Forward-Looking Statements" and "Risk Factors" in this Quarterly Report. Our fiscal year ends on March 31 and our fiscal quarters end on June 30, September 30 and December 31.

Overview

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

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

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

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

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology, hematology and oncology, and modalities, including biologics, topicals, gene therapies and bifunctional small molecules. We currently have 16 Vants and, together, we are advancing a deep and diversified pipeline of over 30 drug candidates. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately $867 million in our publicly traded Vants as of December 31, 2021 (inclusive of the value of certain shares of Myovant Sciences Ltd. as to which Roivant has a return right under certain circumstances). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

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

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

Product Candidate	Indication	Vant	Modality	Phase
Tapinarof	Psoriasis	Dermavant	Topical	Registration
Tapinarof	Atopic Dermatitis	Dermavant	Topical	Phase 3
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 3
Batoclimab	Warm Autoimmune Hemolytic Anemia	Immunovant	Biologic	Phase 2
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 2
Batoclimab	Indication #4	Immunovant	Biologic	Phase 2
Batoclimab	Indication #5	Immunovant	Biologic	Phase 2
ARU-1801	Sickle Cell Disease	Aruvant	Gene Therapy	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 2
Cerdulatinib	Vitiligo	Dermavant	Topical	Phase 2
RVT-2001	Transfusion-Dependent Anemia in Patients with Lower-Risk MDS	Hemavant	Small Molecule	Phase 1
LSVT-1701	Staph Aureus Bacteremia	Lysovant	Biologic	Phase 1
Cerdulatinib	Atopic Dermatitis	Dermavant	Topical	Phase 1
DMVT-504	Hyperhidrosis	Dermavant	Small Molecule	Phase 1
DMVT-503	Acne	Dermavant	Topical	Preclinical
ARU-2801	Hypophosphatasia	Aruvant	Gene Therapy	Preclinical
AFVT-2101	Solid Tumors	Affivant	Biologic	Preclinical
CVT-TCR-01	Oncologic Malignancies	Cytovant	Cell Therapy	Preclinical

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

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

- A quantum mechanics-based molecular dynamics software platform to predict the interactions, energies and conformational behavior of targets and generate novel drug candidates;
- A supercomputing cluster composed of over 700 graphics processing units;
- A suite of degrader-specific ML tools;
- A wet lab fully equipped for synthetic chemistry, crystallography, biophysics, biochemistry and biology.

The following table summarizes our ownership of our subsidiary companies and certain affiliates as of December 31, 2021.

	Roivant Ownership	
Vant	Basic[1]	Fully Diluted[2]
Dermavant	100%	85%
Immunovant	64%[3]	58%[3]
Aruvant	88%	80%
Proteovant	60%	55%
Kinevant	88%	83%
Hemavant	100%	100%
Lysovant	100%	99%
Affivant	100%	99%
Cytovant	72%	69%
Arbutus	27%[3]	25%[3]
Sio Gene Therapies	25%[3]	24%[3]
Genevant	83%	67%
Lokavant	90%	84%
Datavant	*	*
Alyvant	97%	95%

Note: Excludes early-stage pipeline of protein degraders and inhibitors being developed through our small molecule discovery engine. All drugs in current pipeline are investigational and subject to health authority approval. Ownership figures as of December 31, 2021. Roivant ownership in Cytovant includes both direct and indirect ownership.

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

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

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

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

Vant	Catalyst	Expected Timing
Dermavant	FDA approval decision on tapinarof for psoriasis	2Q 2022
	Topline data from tapinarof Phase 3 trials in atopic dermatitis	1H 2023
Immunovant	Batoclimab pivotal trial initiation in MG	1H 2022
	Initiate three pivotal programs, including MG	2022
	Progress TED, WAIHA, and two new indications to be announced	2022
Aruvant	New patient and follow-up data from Phase 1/2 trial in sickle cell disease	2022
	ARU-1801 Phase 3 initiation in sickle cell disease	2023
Kinevant	Namilumab Phase 2 initiation in sarcoidosis	1H 2022
Hemavant	Expand ongoing RVT-2001 Phase 1/2 trial in lower-risk MDS	1H 2022
	Initial data from RVT-2001 Phase 1/2 trial in lower-risk MDS	2023
Lysovant	LSVT-1701 MAD initiation in *Staph aureus* Bacteremia	1H 2022
Proteovant	Phase 1 initiation for first degrader candidate	2022
Roivant / Proteovant	Multiple additional degrader candidates entering IND-enabling studies each year	Starting 2022

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

Recent Developments

- **Hemavant:** Roivant has launched a new Vant, Hemavant, which entered into a licensing agreement with Eisai Co., Ltd. for exclusive global rights to the investigational agent RVT-2001, a potential first-in-class small molecule SF3B1 modulator. RVT-2001 has achieved a red blood cell transfusion independence rate of over 30% in 19 patients with lower-risk, transfusion-dependent MDS, 15 of whom had documented prior treatment with lenalidomide and/or hypomethylating agents. Hemavant plans to develop RVT-2001 as an oral therapy for transfusion-dependent anemia in patients with lower-risk MDS, with a robust open-label expansion of the ongoing Phase 1/2 clinical trial for RVT-2001 in the first half of calendar year 2022.
- **Genevant:** The Federal Circuit Court of Appeals rejected Moderna's appeal of the prior Patent Trial and Appeal Board decision holding all claims of U.S. Patent 8,058,069 patentable. The court also dismissed Moderna's appeal challenging a similar finding of patentability of certain claims of U.S. Patent 9,364,435 for lack of standing. Together, the decisions confirm the strength of Genevant's nucleic acid delivery-related patent portfolio.
- **Dermavant:** Dermavant's NDA submission for tapinarof remains on track, with no expectation of an FDA advisory committee and an assigned PDUFA date in Q2 2022. Dermavant continues to build out its organization, with key commercial leadership in place, and manufacturing remains on track for launch upon FDA approval. In December 2021, results from the PSOARING 1 and PSOARING 2 pivotal trials of tapinarof in plaque psoriasis were published in The New England Journal of Medicine. In January 2022, Dermavant presented patient satisfaction data demonstrating consistently high rates of satisfaction and positive perception of treatment with tapinarof, with 81.1% preferring tapinarof to topical drugs used in the past and 67.8% preferring tapinarof to systemic drugs used in the past.
- **Aruvant:** Punam Malik, M.D., Director of the Cincinnati Comprehensive Sickle Cell Center and Program Leader of the Hematology and Gene Therapy Program at the Cincinnati Children's Hospital Medical Center, presented data highlighting the clinically meaningful reduction in vaso-occlusive events for participants in the ongoing ARU-1801 Phase 1/2 trial and the unique attributes that contribute to the potency of ARU-1801 at the American Society of Hematology (ASH) Annual Meeting on December 13, 2021.
- **Immunovant:** In December 2021, Immunovant announced it had achieved alignment with the FDA Division of Neurology 1 to move forward in myasthenia gravis. The Phase 3 trial will include an induction (primary efficacy) period during which Immunovant plans to study doses of 680mg and 340mg of batoclimab delivered weekly by subcutaneous injection, followed by alternative dosing regimens (including potential lower maintenance and higher rescue doses) in subsequent study periods. The trial is designed to address unmet patient needs by leveraging batoclimab's broad therapeutic window and simple subcutaneous delivery device to provide a differentiated treatment option.
- **Kinevant:** In December 2021, the FDA cleared the IND submitted by Kinevant for a Phase 2 trial evaluating namilumab for the treatment of sarcoidosis.
- **Lysovant:** In January 2022, the FDA cleared the IND submitted by Lysovant for a multiple ascending dose study of LSVT-1701 in patients with complicated *Staph aureus* bacteremia including infective endocarditis.

Impact of COVID-19

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

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

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

Components of Results of Operations

Revenue, net

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

Cost of revenues

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

Research and development expenses

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

- Program-specific costs, including:
  - direct third-party costs, which include expenses incurred under agreements with contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, and any other third-party expenses directly attributable to the development of our product candidates; and
  - payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

- Consideration for the purchase of in-process research and development ("IPR&D") through asset acquisitions and license agreements, including:
  - cash upfront payments;
  - shares and other liability instruments issued; and
  - fair value of future contingent consideration payments.
- Unallocated internal costs, including:
  - employee-related expenses, such as salaries, share-based compensation, and benefits, for research and development personnel; and
  - other expenses, including consulting costs, that are not allocated to a specific program.

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

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

- the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of our product candidates, and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;
- the number of doses that patients receive;
- the countries in which the trials are conducted;
- our ability to secure and leverage adequate CRO support for the conduct of clinical trials;
- our ability to establish an appropriate safety and efficacy profile for our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the significant and changing government regulation and regulatory guidance;
- our ability to establish clinical and commercial manufacturing capabilities, or make arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations due to the COVID-19 pandemic; and
- our ability to maintain a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates. In addition, the probability of success for our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability.

General and administrative expenses

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

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

Change in fair value of investments

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

Gain on sale of investment

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

Change in fair value of debt and liability instruments

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

Gain on termination of Sumitomo Options

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

Other (income) expense, net

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

Income tax expense (benefit)

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

Net loss attributable to noncontrolling interests

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

Results of Operations

Comparison of the three and nine months ended December 31, 2021 and 2020

The following table sets forth our results of operations for the three months ended December 31, 2021 and 2020:

	Three Months Ended December 31,		
	2021	2020	Change
	(in thousands)		
Revenue, net	$ 24,341	$ 5,750	$ 18,591
Operating expenses:			
Cost of revenues	1,384	684	700
Research and development	153,450	202,261	(48,811)
General and administrative	115,530	61,875	53,655
Total operating expenses	270,364	264,820	5,544
Loss from operations	(246,023)	(259,070)	13,047
Change in fair value of investments	38,036	18,235	19,801
Change in fair value of debt and liability instruments	23,017	4,304	18,713
Other income, net	(1,029)	(5,788)	4,759
Loss before income taxes	(306,047)	(275,821)	(30,226)
Income tax expense (benefit)	38	(224)	262
Net loss	(306,085)	(275,597)	(30,488)
Net loss attributable to noncontrolling interests	(21,549)	(14,568)	(6,981)
Net loss attributable to Roivant Sciences Ltd.	$ (284,536)	$ (261,029)	$(23,507)

The following table sets forth our results of operations for the nine months ended December 31, 2021 and 2020:

	Nine Months Ended December 31,		
	2021	2020	Change
	(in thousands)		
Revenue, net	$ 46,063	$ 8,649	$ 37,414
Operating expenses:			
Cost of revenues	8,507	1,579	6,928
Research and development	486,335	358,404	127,931
General and administrative	636,060	178,730	457,330
Total operating expenses	1,130,902	538,713	592,189
Loss from operations	(1,084,839)	(530,064)	(554,775)
Change in fair value of investments	14,382	(107,210)	121,592
Gain on sale of investment	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	40,747	31,577	9,170
Gain on termination of Sumitomo Options	(66,472)	—	(66,472)
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	—	(115,364)	115,364
Other expense (income), net	2,529	(3,703)	6,232
Loss before income taxes	(632,271)	(335,364)	(296,907)
Income tax expense	532	1,708	(1,176)
Net loss	(632,803)	(337,072)	(295,731)
Net loss attributable to noncontrolling interests	(57,603)	(37,402)	(20,201)
Net loss attributable to Roivant Sciences Ltd.	$ (575,200)	$ (299,670)	$(275,530)

Variance analysis for three and nine months ended December 31, 2021 and 2020

Revenue, net

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
	(in thousands)			*(in thousands)*		
Revenue, net	$ 24,341	$ 5,750	$18,591	$ 46,063	$ 8,649	$37,414

Revenue, net increased by $18.6 million to $24.3 million for the three months ended December 31, 2021 compared to $5.8 million for the three months ended December 31, 2020, primarily related to the recognition of milestone income as well as payment for the license of technology. Revenue generated was not significant in either period presented.

Revenue, net increased by $37.4 million to $46.1 million for the nine months ended December 31, 2021 compared to $8.6 million for the nine months ended December 31, 2020, primarily related to payments received in connection with license agreements and the license of technology. Additionally, we recognized revenue relating to the sales of clinical product as well as milestone income at Dermavant. Revenue generated was not significant in either period presented.

Cost of revenues

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
	(in thousands)			*(in thousands)*		
Cost of revenues	$ 1,384	$ 684	$ 700	$ 8,507	$ 1,579	$6,928

Cost of revenues increased by $0.7 million to $1.4 million for the three months ended December 31, 2021 compared to $0.7 million for the three months ended December 31, 2020. Cost of revenues was not significant in either period presented.

Cost of revenues increased by $6.9 million to $8.5 million for the nine months ended December 31, 2021 compared to $1.6 million for the nine months ended December 31, 2020, primarily due to cost associated with the sales of clinical product. Cost of revenues was not significant in either period presented.

Research and development expenses

For the three months ended December 31, 2021 and 2020**,** our research and development expenses consisted of the following:

	Three Months Ended December 31,		
	2021	2020	Change
		(in thousands)	
Program-specific costs:			
Tapinarof	$ 14,242	$ 7,697	$ 6,545
Batoclimab	20,191	15,325	4,866
ARU-1801	7,407	4,153	3,254
Gimsilumab	181	4,418	(4,237)
Other program-specific costs	45,684	7,303	38,381
Total program-specific costs	87,705	38,896	48,809
Consideration for the purchase of IPR&D through asset acquisitions and license agreements	14,105	146,452	(132,347)
Unallocated internal costs:			
Share-based compensation	17,669	3,754	13,915
Personnel-related expenses	27,050	10,955	16,095
Other expenses	6,921	2,204	4,717
Total research and development expenses	$ 153,450	$ 202,261	$ (48,811)

For the nine months ended December 31, 2021 and 2020**,** our research and development expenses consisted of the following:

	Nine Months Ended December 31,		
	2021	2020	Change
		(in thousands)	
Program-specific costs:			
Tapinarof	$ 91,655	$ 25,016	$ 66,639
Batoclimab	47,358	38,183	9,175
ARU-1801	17,158	15,693	1,465
Gimsilumab	3,634	23,921	(20,287)
Other program-specific costs	88,461	22,114	66,347
Total program-specific costs	248,266	124,927	123,339
Consideration for the purchase of IPR&D through asset acquisitions and license agreements	96,212	191,791	(95,579)
Unallocated internal costs:			
Share-based compensation	47,441	6,760	40,681
Personnel-related expenses	72,902	31,108	41,794
Other expenses	21,514	3,818	17,696
Total research and development expenses	$ 486,335	$ 358,404	$127,931

Research and development expenses decreased by $48.8 million to $153.5 million for the three months ended December 31, 2021 compared to $202.3 million for the three months ended December 31, 2020, primarily due to a decrease in consideration for the purchase of IPR&D through asset acquisitions and license agreements of $132.3 million, partially offset by increases in program-specific costs of $48.8 million, personnel-related expenses of $16.1 million, and share-based compensation of $13.9 million.

The decrease of $132.3 million in consideration for the purchase of IPR&D was primarily due to multiple asset acquisitions and license agreements entered into during the three months ended December 31, 2020, partially offset by consideration for the purchase of IPR&D of $14.1 million relating to a license agreement with Eisai Co., Ltd. (“Eisai”), which was entered into during the three months ended December 31, 2021.

The increase of $48.8 million in program-specific costs was primarily due to an increase in other program-specific costs of $38.4 million. This increase in other program-specific costs was primarily due to higher preclinical and clinical costs associated with our programs.

The increase of $16.1 million in personnel-related expenses was primarily driven by an increase in headcount to support the progression of our programs and drug discovery.

The increase of $13.9 million in share-based compensation expense was primarily due to the ongoing vesting of certain equity instruments for which the liquidity event vesting condition was met upon the closing of our business combination (the "Business Combination") with Montes Archimedes Acquisition Corp. ("MAAC"), a special purpose acquisition company. We did not recognize share-based compensation expense related to these equity instruments during the three months ended December 31, 2020 as the liquidity event requirement had not been met and was not deemed probable of being met.

Research and development expenses increased by $127.9 million to $486.3 million for the nine months ended December 31, 2021 compared to $358.4 million for the nine months ended December 31, 2020, primarily due to increases in program-specific costs of $123.3 million, personnel-related expenses of $41.8 million, and share-based compensation of $40.7 million, partially offset by a decrease in consideration for the purchase of IPR&D through asset acquisitions and license agreements of $95.6 million.

The increase of $123.3 million in program-specific costs was primarily due to an increase of $66.6 million for Dermavant's tapinarof program, largely resulting from a one-time milestone expense of $39.3 million due to the achievement of a development milestone and purchases of clinical product as we prepare for potential commercial launch and incur costs associated with our Phase 3 clinical program in atopic dermatitis. Additionally, other program-specific costs increased by $66.3 million, primarily due to higher preclinical and clinical costs associated with our programs. These increases were partially offset by a decrease of $20.3 million for Kinevant's gimsilumab program primarily as a result of higher costs during the nine months ended December 31, 2020 related to our study in COVID-19 Associated ARDS.

The decrease of $95.6 million in consideration for the purchase of IPR&D was primarily due to multiple asset acquisitions and license agreements entered into during the nine months ended December 31, 2020, partially offset by consideration for the purchase of IPR&D of $82.1 million relating to an asset acquisition completed by Priovant, Inc. and $14.1 million relating to a license agreement with Eisai, which were entered into during the nine months ended December 31, 2021.

The increase of $40.7 million in share-based compensation expense was primarily due to the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $22.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination and continued recognition of expense over the requisite service periods. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met.

The increase of $41.8 million in personnel-related expenses was primarily driven by an increase in headcount to support the progression of our programs and drug discovery.

General and administrative expenses

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
General and administrative	$ 115,530	$ 61,875	$53,655	$ 636,060	$ 178,730	$457,330

General and administrative expenses increased by $53.7 million to $115.5 million for the three months ended December 31, 2021 compared to $61.9 million for the three months ended December 31, 2020. The increase was largely due to an increase in share-based compensation expense of $40.0 million, primarily as a result of the ongoing vesting of certain equity instruments for which the liquidity event vesting condition was met upon the closing of the Business Combination. We did not recognize share-based compensation expense related to these equity instruments during the three months ended December 31, 2020 as the liquidity event requirement had not been met and was not deemed probable of being met. Additionally, general and administrative expenses for Dermavant have increased as we prepare for a potential commercial launch.

General and administrative expenses increased by $457.3 million to $636.1 million for the nine months ended December 31, 2021 compared to $178.7 million for the nine months ended December 31, 2020. The increase was largely due to an increase in share-based compensation expense of $401.6 million primarily as a result of the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination, resulting in the recognition of a one-time catch-up expense of $350.0 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination and continued recognition of expense over the requisite service periods. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met. Legal and other professional and consulting fees increased by $18.8 million in part to support our higher operating activities as we prepared to operate as a public company. Additionally, general and administrative expenses for Dermavant have increased as we prepare for a potential commercial launch.

Change in fair value of investments

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Change in fair value of investments	$ 38,036	$ 18,235	$19,801	$ 14,382	$ (107,210)	$121,592

Change in fair value of investments was an unrealized loss of $38.0 million and $18.2 million for the three months ended December 31, 2021 and 2020, respectively. The change of $19.8 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant.

Change in fair value of investments was an unrealized loss of $14.4 million and an unrealized gain of $107.2 million for the nine months ended December 31, 2021 and 2020, respectively. The change of $121.6 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant following the completion of the Datavant Merger in July 2021.

Gain on sale of investment

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on sale of investment	$ —	—	$ —	$ (443,754)	$ —	$(443,754)

Gain on sale of investment was $443.8 million for the nine months ended December 31, 2021 due to the Datavant Merger in July 2021 at which point we received approximately $320 million in cash and a minority equity stake in the combined company. See “Components of Results of Operations —Gain on sale of investment” above for additional information.

Change in fair value of debt and liability instruments

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Change in fair value of debt and liability instruments	$ 23,017	$ 4,304	$18,713	$ 40,747	$ 31,577	$9,170

Change in fair value of debt and liability instruments was an unrealized loss of $23.0 million and $4.3 million for the three months ended December 31, 2021 and 2020, respectively. Change in fair value of debt and liability instruments for the three months ended December 31, 2021 primarily consisted of an unrealized loss of $17.3 million relating to the warrants issued as part of the Business Combination. Change in fair value of debt and liability instruments for the three months ended December 31, 2020 primarily consisted of an unrealized loss of $27.2 million relating to the NovaQuest Facility, partially offset by an unrealized gain of $23.2 million relating to the Sumitomo Options.

Change in fair value of debt and liability instruments was an unrealized loss of $40.7 million and $31.6 million for the nine months ended December 31, 2021 and 2020, respectively. Change in fair value of debt and liability instruments for the nine months ended December 31, 2021 primarily consisted of an unrealized loss of $21.8 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, and an unrealized loss of $17.3 million relating to the warrants issued as part of the Business Combination. Change in fair value of debt and liability instruments for the nine months ended December 31, 2020 primarily consisted of an unrealized loss of $57.2 million relating to the NovaQuest Facility, partially offset by an unrealized gain of $27.4 million relating to the Sumitomo Options.

Gain on termination of Sumitomo Options

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on termination of Sumitomo Options	$ —	—	$ —	$ (66,472)	$ —	$(66,472)

Gain on termination of Sumitomo Options was $66.5 million for the nine months ended December 31, 2021 due to the completion of transactions contemplated by the Asset Purchase Agreement entered into with Sumitomo and SPC. See "Components of Results of Operations—Gain on termination of Sumitomo Options" above for additional information.

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2021	2020	Change	2021	2020	Change
		(in thousands)			*(in thousands)*	
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	$ —	—	$ —	$ —	$ (115,364)	$115,364

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity was $115.4 million for the nine months ended December 31, 2020, primarily due to a gain of $86.5 million on the deconsolidation of Datavant in April 2020 and a gain of $28.8 million resulting from the remeasurement of our previously held interest in Genevant upon its consolidation in July 2020.

Liquidity and Capital Resources

Overview

For the nine months ended December 31, 2021 and 2020, we incurred net losses of $632.8 million and $337.1 million, respectively. As of December 31, 2021, we had cash and cash equivalents of approximately $2.2 billion and our accumulated deficit was approximately $2.5 billion. We have not generated any revenues to date from the sale of our product candidates. Our revenue, primarily generated through license agreements as well as from subscription and service-based fees, has not been significant to date. Our operations to date have been financed primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements.

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

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

In July 2021, Proteovant Sciences, Inc. ("Proteovant") collected the subscription receivable relating to the second $100.0 million payment due under a subscription agreement entered into with SK, Inc. ("SK") in December 2020.

In May 2021, Dermavant and certain of its subsidiaries entered in a $40.0 million senior secured credit facility with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent.

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

- fund preclinical studies and clinical trials for our product candidates, which we are pursuing or may choose to pursue in the future;

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

Cash Flows

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

	Nine Months Ended December 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (530,260)	$ (446,071)
Net cash provided by (used in) investing activities	$ 308,997	$ (27,612)
Net cash provided by financing activities	$ 305,722	$ 357,550

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 nine months ended December 31, 2021, cash used in operating activities increased by $84.2 million to $530.3 million compared to the nine months ended December 31, 2020. This increase was primarily driven by an increase in cash required to fund operations, particularly as a result of the progression of Vant programs and payments made for a one-time milestone expense and purchases of clinical product as we prepare for a potential commercial launch and incur costs associated with our Phase 3 clinical program in atopic dermatitis at Dermavant. Additionally, in November 2021, we made a $50.0 million cash payment related to the previously-disclosed $100.0 million second tranche of consideration due in connection with the acquisition of Silicon Therapeutics, LLC. The remaining consideration was settled by the issuance of 6,348,057 of our common shares.

Investing Activities

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

For the nine months ended December 31, 2021, cash flow from investing activities changed by $336.6 million to net cash provided by investing activities of $309.0 million from net cash used in investing activities of $27.6 million for the nine months ended December 31, 2020. This change in cash flow from investing activities is primarily due to approximately $320 million in cash we received as a result of the Datavant Merger.

Financing Activities

For the nine months ended December 31, 2021, cash provided by financing activities decreased by $51.8 million to $305.7 million compared to the nine months ended December 31, 2020. During the nine months ended December 31, 2021, proceeds were generated by the completion of our Business Combination and PIPE financing in September 2021, payment of the subscription receivable due to Proteovant by SK in July 2021, and the senior secured credit facility entered into by Dermavant and certain of its subsidiaries with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent, partially offset by cash used to repay all amounts outstanding under a previously existing loan and security agreement with Hercules Capital, Inc. During the nine months ended December 31, 2020, cash provided by financing activities was primarily driven by the issuance of equity at our majority-owned subsidiary Immunovant, Inc.

Outlook

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

Contractual Obligations and Commitments

During the nine months ended December 31, 2021, there were no material changes outside the ordinary course of business to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations of Roivant for the year ended March 31, 2021 in our Proxy Statement / Prospectus.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The preparation of these unaudited condensed consolidated 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 unaudited condensed consolidated 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. During the nine months ended December 31, 2021, there were no material changes to our critical accounting policies and use of estimates from those disclosed under Management’s Discussion and Analysis of Financial Condition and Results of Operations of Roivant for the year ended March 31, 2021 in our Proxy Statement / Prospectus.

Recently Adopted Accounting Pronouncements

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

JOBS Act

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. 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 Principal Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and our Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021, the end of the period covered by this Quarterly Report. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

Our management, including our Principal Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

PART II—OTHER INFORMATION

Item 1. 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 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.

For a description of our legal proceedings, refer to "Note 9—Commitments and Contingencies" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

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 Quarterly Report, including our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report, 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 may make it difficult for us to execute on our business model and for you to assess our future viability. We have never generated product revenue from the commercialization of our drug product candidates, and there is no guarantee that we will do so in the future.

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

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

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

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

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

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

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to predict the timing or amount of increased expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in

addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our product candidates that we may identify. Even if a product is approved for commercial sale, we could incur significant costs associated with the commercial launch of any such product.

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

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

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

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

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

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

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

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

- delays or difficulties in enrolling patients in our clinical trials, and the consequences of such delays or difficulties, including terminating clinical trials prematurely;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- delays or disruptions in non-clinical experiments due to unforeseen circumstances at contract research organizations ("CROs"), and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable non-U.S. regulatory agencies, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical studies, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- other disruptions to our business generally, including from the transition to remote working for the majority of our employees and the implementation of new health and safety requirements for our employees; and
- waiver or suspension of patent or other intellectual property rights.

These and other factors arising from the COVID-19 pandemic, including risks relating to the emergence of new variants of SARS-CoV-2, including the Delta and Omicron variants, the efficacy and availability of vaccines and rates of vaccination (including vaccine booster shots), the pandemic worsening in countries that are already afflicted with COVID-19 or the COVID-19 pandemic continuing to spread to additional countries or returning to countries where the pandemic has been partially contained, could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

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

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

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

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

Our drug discovery efforts are centered on our targeted protein degradation platform and our computational discovery technology. As a company we have relatively limited experience in drug discovery generally, with targeted protein degradation as an approach to target inhibition and with computational discovery as a technology. Our future success depends, in part, on our ability to successfully use targeted protein degradation and computational discovery technology to identify promising new product candidates.

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

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

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

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

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

Additionally, we may pursue additional in-licenses or acquisitions of product candidates or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We face risks associated with the Vant structure.

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

Operating the Vants independently, rather than under a centralized, consolidated management team, may result in increased costs at the Vants, as certain functions or processes, including clinical and non-clinical personnel, business development, finance, accounting, human resources and legal functions, are replicated across the Vants. There may also be certain start-up costs, associated with the establishment of a new Vant or integration of a newly acquired business into a Vant, which are greater under the Vant model than they would be under a centralized model. The use of the Vant model may also entail increased costs for us, including the time and expenses associated with hiring Vant CEOs and management teams, overseeing Vant equity incentive arrangements and managing

compliance-related risks, including the internal controls, reporting systems and procedures necessary for us to operate as a public company. We may also be exposed to increased "key employee" risks, in the event a Vant CEO were to depart, including the loss of other senior Vant personnel, potentially resulting in significant delays to the development programs at the Vant. These increased expenses, complexities and other challenges may make using and scaling the Vant model more challenging and costly than it would be for a traditional pharmaceutical company to both operate and expand the number of product candidates under development, which could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects. This decentralized model could also make compliance with applicable laws and regulations more challenging to monitor and may expose us to increased costs that could, in turn, harm our business, financial condition, results of operations or prospects.

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

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

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

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

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

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

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

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

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

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

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our or our subsidiaries' equity securities which would result in dilution to our shareholders;

- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates, intellectual property, and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- with respect to our biopharmaceutical product candidates:
  - the cost and timing of newly launched product candidates or Vants;
  - the initiation, timing, progress, costs and results of pre-clinical studies and clinical trials for our product candidates;
  - the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable non-U.S. regulatory authorities globally;

- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
- the cost and timing of completion of pre-clinical, clinical and commercial manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our product candidates on our own;
- the initiation, progress, timing and results of our commercialization of our product candidate, if approved for commercial sale; and
- other costs associated with preparing the commercial launch of our product candidates;

- for our healthcare and drug discovery technologies:
  - the costs related to hiring and retaining employees with the expertise necessary to manage these technologies;
  - investments in wet labs, computational resources and other facilities; and
  - the costs needed to update, maintain and improve these technologies and the infrastructure underlying these technologies, including with respect to data protection and cybersecurity.

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

We expect that significant additional capital will be needed in the future to continue our planned operations, including with respect to fulfilling our and the Vants' human resources needs, which may be costly. Until such time, if ever, that we can generate substantial revenues, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations both at our parent and at certain affiliates. To the extent that we raise additional capital by issuing equity securities at the parent or subsidiary level, our existing shareholders' ownership, or our ownership in our subsidiaries, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. The foregoing restrictions associated with potential sources of additional capital may make it more difficult for us to raise additional capital or to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, if and when we require it, our ability to grow or support our business and to respond to business challenges could be significantly limited.

Risks Related to the Development of Our Product Candidates

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

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

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

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

Failures can occur at any stage of clinical trials or pre-clinical studies, and we could encounter problems that cause us to abandon or repeat clinical trials or pre-clinical studies. In addition, results from clinical trials or pre-clinical studies may require further evaluation, delaying the next stage of development or submission of an IND or an NDA or similar application. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in pre-clinical or early-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials or studies. Likewise, the results of early clinical trials or pre-clinical studies of our product candidates may not be predictive of the results of planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results.

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

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

- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the FDA, the EMA and other comparable regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other comparable regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

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

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

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

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

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

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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

Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior pre-clinical testing and clinical trials. In particular, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our clinical trials of batoclimab will be observed in any future clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results in earlier pre-clinical studies or clinical trials. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. In February 2021, our subsidiary, Immunovant, voluntarily paused dosing in its clinical trials for batoclimab globally due to elevated total cholesterol and LDL levels observed in patients treated with batoclimab, resulting in a delay in Immunovant’s development of batoclimab. Immunovant has initiated discussions with the FDA and achieved alignment with the FDA’s Division of Neurology 1 in December 2021 to move forward in Myasthenia Gravis (“MG”). Immunovant plans to start its Phase 3 study for batoclimab in MG in the first half of calendar year 2022. Immunovant continues to evaluate potential new indications for batoclimab and remains on track to announce two new indications by August 2022. Immunovant expects two of our four indications beyond MG to be initiated as a pivotal trial in the calendar year 2022. Failure to successfully complete clinical trials of batoclimab and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab would significantly harm our business.

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

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

From time to time, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously published. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares.

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

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

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

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

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

We and our CROs will be required to comply with the Good Laboratory Practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and other comparable non-U.S. regulatory authorities, which also require compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines for any of our product candidates that are in pre-clinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we may rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our expected reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable non-U.S. regulatory authorities may reject our marketing applications and require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Failure by any future CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies.

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

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

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

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

Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our product candidates or any future product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our pre-clinical studies, clinical trials, research and development operations and commercialization. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates 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 product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involves committing substantial financial resources to current or future potential product candidates that may never be approved or achieve commercialization at scale or at all.

In addition, legislative, executive and regulatory proposals are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the United States on foreign supply chains and manufacturing. While we are still assessing these developments, they could impact our selection and utilization of CMOs, vendors and other suppliers and could have a material adverse impact on our business, financial condition and results of operations.

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

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

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations and standards, including cGMP and similar standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacturer of another company's product candidates;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our product candidates under specified storage conditions and in a timely manner.

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

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

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products

approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in the issuance of inspectional observations on FDA's Form-483, Warning or Untitled Letters, similar communications/objections by other authorities, public safety alerts identifying our company or products and sanctions being imposed on us, including clinical holds, import alerts, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

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

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

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

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

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

A potentially significant risk in any gene therapy product candidate using viral vectors is that the vector will insert in or near cancer-causing oncogenes leading to uncontrolled clonal proliferation of mature cancer cells in the patient, known as insertional oncogenesis, which can lead to certain forms of cancer. In early 2021, a company developing a gene therapy for the treatment of sickle cell disease announced that one of its patients has developed acute myelogenous leukemia following treatment. While Aruvant has not experienced any similar safety events to date, any such events arising in patients treated with ARU-1801 could result in delays to the clinical development timeline, the suspension of clinical development altogether or, following approval by the FDA and/or other

relevant regulatory authorities, if received, the product being removed from the market or its market opportunity being significantly reduced. In addition, the sickle cell disease population has an elevated underlying risk of malignancy. As a result, if patients treated with ARU-1801 develop a malignancy, it may be difficult for us to determine the underlying cause of the malignancy and the link, if any, to ARU-1801, potentially causing further delays to our clinical development timeline. Any of the foregoing issues arising in relation to ARU-1801 or other gene therapy product candidates could lead to adverse publicity and have a material adverse effect on our business and the price of our Common Shares.

Risks Related to Regulatory Approval and Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

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

We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable non-U.S. regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable non-U.S. regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

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

Adverse events caused by our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidates or those from other companies targeting similar diseases,

could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. For example, in February 2021, our subsidiary Immunovant voluntarily paused dosing in its ongoing trials for batoclimab globally due to elevated total cholesterol and LDL levels observed in patients treated with batoclimab, resulting in a delay in Immunovant's development of batoclimab. Any of these occurrences may harm our business, financial condition and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, traceability, conduct of potential post-market studies and post-market submission requirements, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, prior notification/review and/or approval of advertising and promotional materials by the competent authorities, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the

indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If a product candidate receives marketing approval, the accompanying label may limit the approved use of the drug or the FDA or other regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning, be included in the product labeling, which could limit sales of the product.

The FDA and other relevant regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and that promotional and advertising materials and communications are truthful and non-misleading. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications and if we do not market our product candidates for their approved indications or in a manner which regulators believe to be truthful and non-misleading, we may be subject to enforcement action. Moreover, in the EU we will be prohibited from promoting prescription-only medicinal products of individuals who are not healthcare professionals. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non-U.S. regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in other jurisdictions.

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

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

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

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

We have sought, or may in the future seek, Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation or orphan drug designation for certain of our product candidates. ARU-1801, a gene therapy in development by Aruvant for the treatment of sickle cell disease, has received orphan drug designation and rare pediatric disease

designation by the FDA, as well as early and proactive development support by the EMA, including the possibility for accelerated assessment and orphan designation by the European Commission. In addition, two gene therapies under development by Sio Gene Therapies, AXO-AAV-GM1, in development for the treatment of GM1 gangliosidosis, and AXO-AAV-GM2, in development for the treatment of GM2 gangliosidosis, also known as Tay-Sachs and Sandhoff diseases, have received rare pediatric disease designation and orphan drug designation (in the case of AXO-AAV-GM1) and rare pediatric disease designation (in the case of AXO-AAV-GM2) from the FDA.

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

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

Regulatory authorities in some jurisdictions, including the United States and the European Economic Area (the "EEA"), may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals annually in the United States or for which there is no reasonable expectation that costs of research and development of the drug for the disease or condition can be recovered by sales of the drug in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same orphan indication for that time period. In the United States, in order for a product to receive orphan drug exclusivity, FDA must not have previously approved a drug considered the same drug for the same orphan indication, or the subsequent drug must be shown to be clinically superior to such a previously approved same drug. The applicable period is seven years in the United States. A similar data exclusivity scheme exists in the EEA. The European Commission, on the basis of a scientific opinion by the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, orphan designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the "normal" data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company's pre-clinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic drug can be marketed for ten years from the first approval of the innovator drug in the EEA; the innovator drug may qualify for an extra year's protection. This additional one year of marketing exclusivity may be obtained where the innovator company is granted a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic company can only market their product after 11 years from the first grant of the innovator company's marketing authorization for the product in the EEA.

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

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

If we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the 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. Upcoming legislative reforms in the EU may result in a reduction of market exclusivity periods for orphan medicinal products, changes to the concept of unmet medical need and/or imposition of additional requirements for grant of such exclusivity.

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

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

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

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

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

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

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

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

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway under section 351(k) of the Public Health Service Act ("PHSA") for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, a section 351(k) application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference

product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product submitted under section 351(a) of the PHSA containing the competing sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA and the FDA only approved the first interchangeable biosimilar in July 2021. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples legislation, purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, including by allowing generic drug, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biological product samples. While the full impact of these provisions is unclear at this time, its provisions do have the potential to facilitate the development and future approval of biosimilar versions of our products, introducing biosimilar competition that could have a material adverse impact on our business, financial condition and results of operations.

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

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

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

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

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

- the inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

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

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

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

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

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program (such as Medicare and Medicaid). The term “remuneration” has been broadly interpreted by the federal government to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain activities from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal false claims laws, including the False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim; or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties currently ranging from $11,665 to $23,331 for each false claim or statement for penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 ("HIPAA")), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most healthcare providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personal data and health information;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and EU and foreign national laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and several recently passed state laws that require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes, some of which contain ambiguous requirements that government officials have not yet clarified; and EU and foreign national laws prohibiting promotion of prescription-only medicinal products to individuals other than healthcare professionals, governing strictly all aspects of interactions with healthcare professionals and healthcare organizations and requiring public disclosure of transfers of value made to a broad range of stakeholders, including healthcare professionals, healthcare organizations, medical students, physicians associations, patient organizations and editors of specialized press.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other applicable health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or

restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena, civil investigative demand or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

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

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

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

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

through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. These modifications to the safe harbors are being challenged in court and HHS has delayed their implementation until January 1, 2023; however, the rule may be repealed through legislative action before such time. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Several pending legislative efforts, including President Biden's larger Build Back Better legislative agenda and draft bill text, incorporate these drug pricing reforms in addition to inflationary rebates on Part B and Part D drugs that would be payable on commercial and governmental program utilization, policies aimed at redesigning the Medicare Part D benefit and adopting drug price transparency measures. Recent federal legislation and actions by state and local governments in the United States may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

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

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

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

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

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

Market acceptance and sales of any approved product candidates that we develop will depend in part on the extent to which coverage and adequate reimbursement for these product candidates and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. The target patient populations for our drugs are often relatively small, as a result of which the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our product candidates. There is no assurance that our product candidates, if approved, would achieve adequate coverage and reimbursement levels.

In the United States, no uniform policy of coverage and reimbursement for product candidates exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide

coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product candidates. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our product candidates, to the extent that patients who are prescribed our product candidates, if approved, are not separately reimbursed for the cost of the product.

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

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

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

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

We may face competition in the United States for our product candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act ("MMA") contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent implementation of the rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also

issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC"), for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Other Risks Related to Our Business and Industry

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

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold due to impacts of the COVID-19 pandemic, with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. In April 2021, the FDA issued guidance describing how it will request and conduct voluntary remote interactive evaluations of manufacturing and outsourcing facilities as well as facilities involved in non-clinical and clinical research. In November 2021, FDA released an update to its Resiliency Roadmap for FDA Inspectional Oversight, which described the impact of the COVID-19 pandemic on FDA's inspectional activities and its plan for returning to a more consistent state of operations, detailing how FDA exceeded its best-case scenario projections for conducting domestic surveillance oversight activities. With respect to pre-approval inspections, the FDA has been using other tools and approaches where possible, including requesting existing inspection reports from other foreign regulatory partners, requesting information from applicants, and requesting records and other information directly from facilities and other inspected entities. Should the FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel and there are other identified deficiencies, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility without other identified deficiencies, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. If a prolonged government shutdown or disruption to the operations of the FDA occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown or disruption to the operations of the USPTO could prevent the timely review of our patent applications, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Future government shutdowns and similar events could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

Many of the other pharmaceutical and healthcare technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and our business will be harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors.

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

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

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

Many of our competitors are able to devote greater resources to the development, promotion, and sale of their software solutions and services. Third parties with greater available resources and the ability to initiate or withstand substantial price competition could acquire our current or potential competitors. Our competitors may also establish cooperative relationships among themselves or with

third parties that may further enhance their product offerings or resources. If our competitors' products, services or technologies become more accepted than our solutions, if our competitors are successful in bringing their products or services to market earlier than ours, if our competitors are able to respond more quickly and effectively to new or changing opportunities, technologies, or customer requirements, or if their products or services are more technologically capable than ours, then the business and prospects of these Vants could be adversely affected.

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

We and our subsidiaries are from time to time subject to various litigation matters and claims, including regulatory proceedings, administrative proceedings, securities litigation and other lawsuits, and governmental investigations. In addition, we and our subsidiaries may receive requests for information from governmental agencies in connection with their regulatory or investigatory authority or from private third parties pursuant to subpoena. These proceedings may be complex and prolonged, and may occupy the resources of us and our subsidiaries' management and employees. These proceedings are also costly to prosecute and defend and may involve substantial awards or damages payable by us or our subsidiaries if not favorably resolved. We and our subsidiaries may be required to pay substantial amounts or grant certain rights on unfavorable terms in order to settle such proceedings. We also face risks relating to litigation arising from judgments made by us and the Vants as to the materiality of any developments in our businesses, including with respect to pre-clinical and clinical data, and the resulting disclosure (or lack thereof) may give rise to securities litigation.

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

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

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

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

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

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

Our computer systems, as well as those of various third parties on which we presently rely, or may rely on in the future, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, and/or other third parties. Any of the foregoing may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risks of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, sovereign governments and cyber terrorists, have generally increased over time, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world.

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

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

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

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

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

In addition, many states in which we operate have laws that protect the privacy and security of personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act (the "CMIA"), a statute similar to HIPAA that expressly applies to pharmaceutical companies and companies that provide 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 requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information, with limited exceptions, and requires security measures to protect the information. The CMIA authorizes administrative fines and civil penalties of up to $25,000 for willful violations and up to $250,000 if the violation is for purposes of financial gain, as well as criminal fines. In addition, the California Consumer Privacy Act of 2018 (the "CCPA"), which went into effect on January 1, 2020, requires covered businesses to provide substantial disclosures to California residents and to honor such residents' data protection and privacy rights, including the right to opt-out of sales of personal information. The CCPA provides for civil penalties for violations, as well as 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. The CCPA has been amended several times, including by the California Privacy Rights Act (the "CPRA"), a ballot initiative that passed in November 2020 which, among other things, created a new state agency vested with

authority to implement and enforce the CCPA and the CPRA. Effective in most material aspects starting on January 1, 2023, the CPRA expands California residents' rights to limit uses and disclosures of sensitive personal information and gives California residents' a right to opt out of the sharing of certain personal information for targeted online advertising. Virginia and Colorado also have enacted CCPA/CPRA-like laws, the Virginia Consumer Data Privacy Act (the "VDCPA") and the Colorado Privacy Act ("CPA"), to provide their respective residents with similar rights. New legislation anticipated to be enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. The effects on our business of the CMIA, CCPA, CPRA, VDCPA, CPA and other similar state laws and general consumer protection authorities are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Outside of the United States, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in EEA, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on controllers, including *inter alia*: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with data protection rights of data subjects; and (iv) reporting of certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible). The GDPR also prohibits the transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. Until recently, one such data transfer mechanism was the EU-US Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union ("CJEU"). The CJEU upheld the validity of standard contractual clauses ("SCCs") as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA and the U.K., need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. It remains to be seen whether SCCs will remain available and whether additional means for lawful data transfers will become available. Moreover, 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 United Kingdom and EU (*i.e.*, following the United Kingdom's exit from the EU – otherwise known as Brexit), data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the United Kingdom's data protection framework, enabling data transfers from EU member states to the United Kingdom to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data.

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

activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Social media is increasingly being used to communicate about our research, product candidates, investigational medicines and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us.

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act ("the Leahy-Smith Act"), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act was signed into law on September 16, 2011 and includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We are currently and may in the future be subject to third-party pre-issuance submissions of prior art to the USPTO or its equivalents and we or our licensors have in the past, and may in the future, become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the U.S. or in other jurisdictions challenging our patent rights or the patent rights of others. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. For example, three U.S. patents (U.S. Patent

Nos. 8,058,069, 9,364,435 and 9,404,127) relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH, as assignee of Genevant Sciences Ltd. ("Genevant"), exclusively licenses from Arbutus Biopharma Corp. ("Arbutus") were the subject of *inter partes* review proceedings brought by Moderna Therapeutics, Inc. ("Moderna") before the Patent Trial and Appeal Board of the USPTO ("PTAB"). The PTAB upheld all claims of U.S. Patent No. 8,058,069, invalidated some of the claims of U.S. Patent No. 9,364,435 and invalidated all claims of U.S. Patent No. 9,404,127. The United States Court of Appeals for the Federal Circuit (the "Federal Circuit") heard oral arguments with respect to U.S. Patent Nos. 8,058,069 and 9,364,435 in October 2021. On December 1, 2021, the Federal Circuit issued decisions in both proceedings. The Federal Circuit affirmed the PTAB's decision that upheld all claims of U.S. Patent 8,058,069. The Federal Circuit affirmed the PTAB's decision invalidating certain claims of U.S. Patent 9,364,435 but dismissed Moderna's appeal with respect to those claims that the PTAB upheld for lack of standing. The Federal Circuit vacated and remanded the PTAB's decision on U.S. Patent No. 9,494,127. The PTAB's decision with respect to U.S. Patent No. 9,494,127 had been held in administrative abeyance pending a review following a recent Supreme Court ruling in an unrelated case. The matter is now pending before the Federal Circuit and at the briefing stage. Additionally, one European patent (EU patent no. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licenses from Arbutus is the subject of an opposition proceeding brought by Merck Sharp & Dohme Corporation and Moderna at the European Patent Office Opposition Division. 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 or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights or result in our breach of agreements pursuant to which we license such rights to our collaborators or licensees. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." For example, the research resulting in certain of our in-licensed patent rights and technology for certain product candidates was funded in part by the U.S. federal government. As a result, the federal government may have certain rights to such patent rights and technology, which include march-in rights. If the federal government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The federal government's rights may also

permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The federal government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. Further, the recipient of U.S. government funding is required to comply with certain other requirements, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. The U.S. government has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times, or be able to rectify any lapse in compliance with these requirements. Any exercise by the government of any of the foregoing rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

If one of our product candidates is approved by the FDA and if a third party files an application under Section 505(b)(2) or an abbreviated new drug application ("ANDA") under Section 505(j) for a generic product containing any of our product candidates, including tapinarof (which, following the natural expiration of our method of use patent family, will be protected only by our formulation patent), and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic product. A certification under 21 CFR § 314.94(a)(12)(i)(A)(4) that the new product will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties, controls on the origin of the software or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities. In addition, certain open source licenses require

that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our solutions. By the terms of certain open source licenses, if portions of our proprietary software are determined to be subject to an open source license or if we combine our proprietary software with open source software in a certain manner, we could be required to release the source code of our proprietary software and to make our proprietary software available under open source licenses, each of which could reduce or eliminate the effectiveness of our computational discovery efforts. We may also face claims alleging noncompliance with open source license terms or misappropriation or other violation of open source technology. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- actual or anticipated fluctuations in our quarterly and annual financial results or the quarterly and annual financial results of companies perceived to be similar to it;
- changes in the market's expectations about operating results;
- our operating results failing to meet market expectations in a particular period;
- a Vant's operating results failing to meet market expectations in a particular period, which could impact the market prices of shares of a public Vant or the valuation of a private Vant, and in turn adversely impact the trading price of our Common Shares;
- the results of clinical trials or pre-clinical studies conducted by us and the Vants;
- changes in financial estimates and recommendations by securities analysts concerning us, the Vants or the biopharmaceutical industry and market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- changes in laws and regulations affecting our and the Vants' businesses;
- commencement of, or involvement in, litigation involving MAAC or us;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- the volume of our Common Shares available for public sale, which may be limited due to, among other reasons, the extent of redemptions by MAAC stockholders in connection with the consummation of the Business Consummation and the relatively limited free float of our Common Shares, particularly prior to the expiration of the lock-up provisions applicable to our Common Shares following the closing of the Business Combination;
- any significant change in our board of directors or management;

- sales of substantial amounts of our Common Shares directors, executive officers or significant shareholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

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

Our warrant agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our Warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with our company.

Our warrant agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the warrant agreement do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our Warrants shall be deemed to have notice of and to have consented to the forum provisions in our warrant agreement. If any action, the subject matter of which is within the scope the forum provisions of the warrant agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (a "foreign action") in the name of any holder of our Warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an "enforcement action") and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder's counsel in the foreign action as agent for such warrant holder.

This choice-of-forum provision may limit a warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company, which may discourage such lawsuits. Warrant holders who do bring a claim in a court of the State of New York or the United States District Court for the Southern District of New York could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of New York. Alternatively, if a court were to find this provision of our warrant agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

We may amend the terms of the Warrants in a manner that may be adverse to holders of Public Warrants with the approval by the holders of at least 50% of the then outstanding Public Warrants. As a result, the exercise price of your Warrants could be increased, the exercise period could be shortened and the number of shares purchasable upon exercise of a warrant could be decreased, all without your approval.

Our Warrants were initially issued by MAAC in registered form under a warrant agreement between Continental Stock Transfer & Trust Company ("CST"), as warrant agent. In connection with the consummation of the Business Combination, American Stock Transfer & Trust Company assumed CST's responsibilities as warrant agent under the warrant agreement.

The warrant agreement provides that the terms of the Warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correct any mistake or defective provision (ii) amending the provisions relating to cash dividends on common stock as contemplated by and in accordance with the warrant agreement or (iii) adding or changing any provisions with respect to matters or questions arising under the warrant agreement as the parties to the warrant agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the Warrants, provided that the approval by the holders of at least 50% of the then-outstanding Public Warrants is required to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a

manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Warrants, convert the Warrants into cash, shorten the exercise period or decrease the number of our Common Shares purchasable upon exercise of a warrant.

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

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

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

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

As a public company, we are required to provide management's attestation on internal controls as required under Section 404(a) of the Sarbanes-Oxley Act. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us as a privately-held company. If we are not successful in implementing the additional requirements of Section 404(a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

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

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

We may redeem your unexpired Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your Warrants worthless.

We have the ability to redeem outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of our Common Shares is equal to or exceeds $18.00 per share (as adjusted for share sub divisions, share capitalizations, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date they send the notice of redemption to the warrant holders. If and when the Warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares upon exercise of the Warrants is not exempt from registration or qualification under applicable state blue sky laws or if we are unable to effect such registration or qualification. We will use our best efforts to register or qualify such shares under the blue sky laws of the state of residence in those states in which the Warrants were offered by us. Redemption of the outstanding Warrants could force an investor to (i) to exercise their Warrants and pay the exercise price therefor at a time when it may be disadvantageous for an investor to do so, (ii) for an investor to sell their Warrants at the then-current market price when they might otherwise wish to hold their Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of an investors Warrants.

In addition, we may redeem an investor's Warrants at any time after they become exercisable and prior to their expiration at a price of $0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their Warrants prior to redemption for a number of Common Shares determined based on the redemption date and the fair market value of our Common Shares. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants, including because the number of shares received is capped at 0.361 Common Shares per warrant (subject to adjustment) irrespective of the remaining life of the Warrants. None of the Private Placement Warrants will be redeemable by us so long as they are held by the MAAC Sponsor or its permitted transferees.

Our management will have the ability to require holders of our Warrants to exercise such Warrants on a cashless basis, which will cause holders to receive fewer Common Shares upon their exercise of the Warrants than they would have received had they been able to exercise their Warrants for cash.

If we call the Public Warrants for redemption after the redemption criteria have been satisfied, our management will have the option to require any holder that wishes to exercise their warrant (including any Warrants held by the MAAC Sponsor, MAAC's former officers or directors, other purchasers of MAAC's founders' units, or their permitted transferees) to do so on a "cashless basis." If our management chooses to require holders to exercise their Warrants on a cashless basis, the number of Common Shares received by a holder upon exercise will be fewer than it would have been had such holder exercised his warrant for cash. This will have the effect of reducing the potential "upside" of the holder's investment in our company.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are incorporated under the laws of Bermuda. We are centrally managed and controlled in the U.K., and under current U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes.

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

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

We are incorporated under the laws of Bermuda. We currently have subsidiaries in the U.S., U.K., Switzerland, China and certain other jurisdictions. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable taxing authorities. If taxing authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require it to adjust its transfer prices and thereby reallocate its income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If taxing authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase its consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC in the current and future taxable years. In addition, recently finalized U.S. Treasury regulations, of which we are continuing to assess the impact, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On November 23, 2021, we issued 6,348,057 Common Shares to Silicon Therapeutics LLC in connection with the Agreement and Plan of Merger, dated as of February 2, 2021, by and among Roivant, Silicon Insite, Inc., Silicon TX China and Silicon Therapeutics LLC, as consideration in connection with the transaction, with an aggregate value of approximately $50.0 million.

On November 24, 2021, we issued 874,957 Common Shares to a pharmaceutical company in connection with a strategic transaction for with an aggregate value of $7.0 million.

We issued the foregoing securities in transactions not involving an underwriter and not requiring registration under Section 5 of the Securities Act of 1933, as amended, in reliance on the exemption afforded by Section 4(a)(2) thereof.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On February 10, 2022, Patrick Machado, a Class I Director who has served as a member of our Board since 2016, informed us that he does not intend to stand for re-election later this year. We expect that Mr. Machado will conclude his board service on or prior to June 30, 2022. His decision is not the result of any disagreement with the Company. We have a search ongoing for new directors for our Board and will provide an update in due course.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.1#†	Exclusive License Agreement by and between Eisai Co. Ltd. and Pharmavant 7 GmbH, dated as of November 24, 2021				Filed herewith
31.1	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
31.2	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
32.1	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
32.2	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
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 (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.

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 Quarterly Report on Form 10-Q 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ROIVANT SCIENCES LTD.

By: /s/ Matthew Gline
Name: Matthew Gline
Title: Principal Executive Officer

By: /s/ Richard Pulik
Name: Richard Pulik
Title: Principal Financial Officer

By: /s/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Date: February 14, 2022

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE ROIVANT SCIENCES LTD. (THE "COMPANY") HAS DETERMINED THAT THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

EXCLUSIVE LICENSE AGREEMENT

by and between

EISAI CO. LTD.

and

PHARMAVANT 7 GmbH

dated as of November 24, 2021

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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[***]

[***]

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

EXCLUSIVE LICENSE AGREEMENT

This EXCLUSIVE LICENSE AGREEMENT (this "Agreement") is entered into as of November 24, 2021 (the "Effective Date") by and between Eisai Co. Ltd., a Japanese corporation with offices at [***] ("Eisai"), and Pharmavant 7 GmbH, a company organized under the laws of Switzerland and having an address of [***] ("Pharmavant") . For purposes of this Agreement, Eisai and Pharmavant are each referred to herein by name, individually as a "Party" or, collectively, as the "Parties."

RECITALS

WHEREAS, Eisai Controls certain Patents and Know-How Covering the Licensed Compound and Licensed Products (as such terms are defined below);

WHEREAS, Pharmavant has experience in the development and commercialization of pharmaceutical products in the Territory (as defined below);

WHEREAS, Pharmavant is a wholly-owned subsidiary of Roivant Sciences Ltd. ("Roivant Sciences");

WHEREAS, the Parties desire to enter into this Agreement pursuant to which, among other things, Eisai will grant to Pharmavant certain exclusive licenses with respect to the development, manufacture and commercialization of the Licensed Compound and Licensed Products in the Territory for use in the Field (as such terms are defined below), on the terms and subject to the conditions set forth herein; and

WHEREAS, [***].

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the terms with initial letters capitalized, whether used in the singular or plural form, shall have the meanings set forth in this Article 1 or, if not listed below, the respective meanings designated throughout this Agreement.

1.1 "Accounting Standards" means (a) United States Generally Accepted Accounting Principles ("GAAP") or (b) International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board ("IAS/IFRS"), as the case may be, consistently applied.

1.2 “Affiliate” means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this definition only, the term “control” (including, with correlative meanings, the terms “controlled by” and “under common control with”) as used with respect to a Person means: (a) direct or indirect ownership of fifty percent (50%) or more of the voting securities or other voting interest of any Person (including attribution from related parties); or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management and policies of such Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise.

1.3 “Annual Net Sales” means, the aggregate Net Sales by Pharmavant, its Affiliates, and its Sublicensees in the Territory of the Licensed Product in a particular Eisai Fiscal Year, calculated in accordance with Accounting Standards.

1.4 Anti-Corruption Laws” means any local and foreign anti-corruption laws, including the provisions of the United States Foreign Corrupt Practices Act of 1977, as amended, and the UK Bribery Act of 2010, as amended.

1.5 “Applicable Law” means all applicable laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any national, multinational, federal, state, provincial, county, city, or other political subdivision, including, to the extent applicable, GCP, GLP, and GMP, as well as all applicable data protection and privacy laws, rules, and regulations, including, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act and the EU Data Protection Directive (Council Directive 95/46/EC), applicable laws implementing the EU Data Protection Directive and the General Data Protection Regulation (2016/679), as well as all applicable all Anti-Corruption Laws, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1 et seq.), that, in each case, govern or otherwise apply to a Party.

1.6 “Assist” means providing, directly or indirectly, a Third Party with (a) any analysis of any Eisai Product Patents and/or Eisai Patents, or any portion thereof; (b) prior art or analysis of any prior art to any such Patents; (c) any documents in Pharmavant’s possession, custody, or control relating to any such Patents, in whole or in part, or to any prior art to any such Patents; or (d) financial or technical support, in each case, as part of a Challenge of any such Patents.

1.7 “Business Day” means a day that is not a Saturday, a Sunday or a day on which banking institutions in Basel, Switzerland, New York, New York or Tokyo, Japan are required or authorized by Applicable Law to remain closed.

1.8 “Calendar Quarter” means each of the three (3) month periods ending March 31, June 30, September 30, and December 31; provided, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall end on the last day of the Term.

1.9 "Challenge" means to contest or Assist in the contest of the validity or enforceability of any Eisai Product Patents and/or Eisai Patents, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. For the avoidance of doubt, the term "contest" includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patents; (b) citation to the United States Patent and Trademark Office pursuant to 35 U.S.C. § 301 of prior art patents or printed publications or statements of the patent owner concerning the scope of any such Patents; (c) filing a request under 35 U.S.C. § 302 for re-examination of any such Patents; (d) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any such Patents or any portion thereof; (e) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patents or any portion thereof; (f) becoming a party to an interference with an application for any such Patents pursuant to 35 U.S.C. § 135; (f) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against any such Patents in any country; or (g) any foreign equivalents of subsection (a) through (e) applicable in any country.

1.10 "Change of Control" means, with respect to a Party (an "Acquired Party"), the occurrence of any of the following events from and after the Effective Date: [***].

1.11 "Clinical Data" means any and all raw data (together with all clinical trial reports and the results of analyses thereof) derived or generated in any Clinical Trial conducted by or on behalf of a Party pursuant to this Agreement.

1.12 "Clinical Trial" means any human clinical trial conducted with the Licensed Product, including any Phase 1 Clinical Trial, Phase 2 Clinical Trial and Phase 3 Clinical Trial, and any post-marketing clinical trial commenced after Regulatory Approval of the Licensed Product.

1.13 "CMC" means chemistry, manufacturing and controls processes with respect to the Licensed Compound or any Licensed Product, including the chemistry, manufacturing and controls section of any Regulatory Materials for such Licensed Compound or Licensed Product.

1.14 "CMC Development Activities" means all activities pertaining manufacturing development or formulation development, including manufacturing process, for the Licensed Compound or any Licensed Product.

1.15 "Commercialization" means the marketing, promotion, sale (and offer for sale or contract to sell), distribution, importation or other commercial exploitation (including the conduct of pricing and reimbursement activities) of a Licensed Product in the Territory, including the conduct of Medical Affairs Activities. For purposes of clarity, Commercialization shall include any commercial activities conducted in preparation for the launch of a Licensed Product but shall not include Manufacturing. When used as a verb, "Commercialize" means to engage in Commercialization.

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

1.16 "Commercialization Plan" means, with respect to the Licensed Product, the plan for the Commercialization of such Licensed Product in the Territory in a given Eisai Fiscal Year (or in the case of the initial Commercialization Plan, the period through First Commercial Sale and for the [***] period thereafter), as such plan may be amended from time to time in accordance with this Agreement, which Commercialization Plan shall be comprised of two parts: (a) a strategic plan addressing matters including (i) demographics and general market strategies; (ii) specific Commercialization and marketing objectives; (iii) the expected Regulatory Filings to be required and prepared, and the expected timetable for making such Regulatory Filings and (b) a tactical plan (the "Tactical Plan") that includes (i) a marketing plan with advertising and general pricing strategies; and (ii) a timeline for Commercialization activities, including the estimated launch date(s)

1.17 "Commercially Reasonable Efforts" means, with respect to Pharmavant in relation to an obligation under this Agreement applicable to the Licensed Compound or any Licensed Product, such efforts that [***] (which in any event shall not be less than the efforts used by a reasonable international biopharmaceutical company or pharmaceutical company, in each case, that is of comparable size and has comparable resources to Pharmavant), in the performance of a corresponding activity for a similar pharmaceutical compound or product, as applicable, at a similar stage in its research, development, or commercial life as the Licensed Compound or such Licensed Product, and that has commercial and market potential similar to the Licensed Compound or such Licensed Product, taking into account [***].

1.18 "Confidential Information" means, with respect to a Disclosing Party, all confidential and proprietary information, including chemical or biological materials, chemical structures, commercialization plans, correspondence, customer lists, data, development plans, formulae, improvements, Inventions, Know-How, processes, regulatory filings, reports, strategies, techniques, or other information, in each case, that are disclosed by or on behalf of such Disclosing Party to the Receiving Party pursuant to this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by or on behalf of the Disclosing Party in oral, written, visual, graphic, or electronic form. [***].

1.19 "Control," "Controls," or "Controlled" means, with respect to any Patent, Know-How or Confidential Information, the ability of a Party or its Affiliates, as applicable (whether through ownership or license (other than a license granted in this Agreement)) to grant to the other Party the licenses or sublicenses to such Patent or Know-How as provided herein, or to otherwise disclose or grant access to or a right to use or reference such Confidential Information to the other Party, without violating the terms of any then-existing agreement with any Third Party at the time such Party or its Affiliates, as applicable, would first be required hereunder to grant such license, sublicense, access or right to use or reference or make such disclosure. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Patent, Know-How or Confidential Information that, prior to the consummation of a Change of Control of an Acquired

Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such Acquired Party after the Effective Date as a result of such Change of Control unless (a) prior to the consummation of such Change of Control, such Acquired Party or any of its Affiliates also Controlled such Patent, Know-How or Confidential Information, (b) the Know-How, Patents or Confidential Information owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such Change of Control, but after the consummation of such Change of Control, the Acquired Party or any of its Affiliates determines to use or uses any such Patents, Know-How or Confidential Information in the performance of its obligations or exercise of its rights under this Agreement, or (c) such Patents, Know-How or Confidential Information were generated from participation by employees or consultants of such Third Party in furtherance of Development, Manufacturing, Medical Affairs Activities or Commercialization activities with respect to the Licensed Compound or the Licensed Products under this Agreement after such Change of Control, in each of which cases (a), (b) and (c), such Patents, Know-How or Confidential Information will be "Controlled" by such Party for purposes of this Agreement.

1.20 "Cover", "Covered" or "Covering" means, with respect to the Licensed Compound or any Licensed Product and a Patent, that, in absence of a license or sublicense under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such Licensed Compound or Licensed Product would infringe (a) if an issued Patent, a claim of such Patent as issued (without regard to the validity or enforceability of such claim) or (b) if a patent application, a claim included in such patent application in good faith and if it were to issue in its then-current form.

1.21 "Damages" means all losses, costs, claims, damages, judgments, liabilities, and expenses (including reasonable attorneys' fees and other reasonable out-of-pocket costs in connection therewith).

1.22 "Data Security and Privacy Laws" means any Applicable Law relating to the privacy, data protection, integrity, Processing and security of Personal Data, including but not limited to: (a) federal and state Applicable Law, including the Health Insurance Portability and Accountability Act of 1996, as amended and all implementing regulations, (b) state data protection laws, (c) state breach notification laws, (d) the General Data Protection Regulation (EU) 2016/679, and (e) any related Applicable Law implementing the foregoing.

1.23 "Development" means all development activities for the Licensed Compound and any Licensed Products, including (a) the conduct of preclinical, clinical and all other regulatory trials for the Licensed Compound and any Licensed Products; (b) the conduct of all CMC Development Activities; and (c) all other regulatory activities necessary to securing and maintaining the Regulatory Approval for a Licensed Product. For purposes of clarity, "Developing" and "Development" shall have correlative meanings. When used as a verb, "Develop" means to engage in Development.

1.24 "Dollars" or "$" means the legal tender of the United States.

1.25 "Eisai Background Know-How" means any Know-How, other than Eisai Product Know-How, that is Controlled by Eisai or its Affiliates as of the Effective Date or thereafter during the Term and (a) encompasses or relates to the Licensed Compound or any Licensed Product or (b) is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or any Licensed Product; provided, however, that, Know-How related to a total synthesis method for Manufacture of the Licensed Compound or any raw materials thereof shall not be included in Eisai Background Know-How. For clarity, Eisai Background Know-How expressly excludes Eisai Inventions and Joint Inventions.

1.26 "Eisai Background Patents" means any Patents, other than Eisai Product Patents, that are Controlled by Eisai or its Affiliates as of the Effective Date or during the Term and (a) Cover the Licensed Compound or any Licensed Product; (b) are necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Products; or (c) claim any Eisai Background Know-How. For clarity, (i) the Eisai Background Patents as of the Effective Date consist of the Patents listed in Schedule 1.26 attached hereto and (ii) Eisai Background Patents expressly exclude Eisai Invention Patents and Joint Patents.

1.27 "Eisai Fiscal Year" means each successive period of twelve (12) months commencing on April 1 and ending on March 31; provided, that, the first Eisai Fiscal Year of the Term shall begin on the Effective Date and end on March 31 of the then-current Eisai Fiscal Year and the last Eisai Fiscal Year of the Term shall begin on the first day of such Eisai Fiscal Year and end on the last day of the Term.

1.28 "Eisai Invention" means any Invention, other than Eisai Product Know-How, that is conceived or reduced to practice solely by any employee, agent or independent contractor of Eisai or its Affiliates. For clarity, Eisai Invention expressly excludes (a) Eisai Background Know-How and Joint Inventions and (b) any Invention related to a total synthesis method for Manufacture of the Licensed Compound or any raw materials thereof.

1.29 "Eisai Invention Patents" means any Patents, other than Eisai Product Patents, Controlled by Eisai during the Term that claim Eisai Inventions. For clarity, Eisai Invention Patents expressly exclude Eisai Background Patents and Joint Patents.

1.30 "Eisai IP" means, collectively, the Eisai Patents, the Eisai Background Know-How and the Eisai Inventions.

1.31 "Eisai Manufacturers" means any and all Eisai subcontractors identified in Schedule 1.31.

1.32 "Eisai Ongoing Clinical Trial" means [***].

1.33 "Eisai Patents" means, collectively, the Eisai Background Patents and the Eisai Invention Patents.

1.34 "Eisai Product Know-How" means (a) any Know-How that is Controlled by Eisai or its Affiliates as of the Effective Date or during the Term and (b) any Invention that is, in either case, specifically directed to (i) the composition of matter of a Licensed Compound or Licensed Product or (ii) a (A) formulation, (B) product by process, (C) polymorph, or (D) method of use or treatment, manufacture, preparation or administration, each of (A) through (D) above, of a Licensed Compound or Licensed Product; [***]. For the avoidance of doubt, Eisai Product Know-How does not include any Know-How or Invention that is directed to a formulation, product by process, method of use or treatment, manufacture, preparation or administration or biomarker that is not solely directed to the Licensed Compound or Licensed Product.

1.35 "Eisai Product Patents" means any Patents that are Controlled by Eisai or its Affiliates as of the Effective Date or during the Term (a) that have claims specifically directed to (i) the composition of matter of a Licensed Compound or Licensed Product or (ii) a (A) formulation, (B) polymorph, or (C) method of use or treatment, or administration of, each of (A) or (B), of a Licensed Compound or Licensed Product; and (b) that are either listed in Schedule 1.35 or that claim any Eisai Product Know-How and, in either case, any Eisai Patents that claim priority from such Patents that are filed, granted or issued during the Term. [***].

1.36 "EU" means all countries that are officially recognized as member states of the European Union at any particular time; [***].

1.37 "EU Regulatory Approval" means, with respect to a Licensed Product and a particular Indication: (a) Regulatory Approval of such Licensed Product for such Indication in three (3) Major European Markets, by the European Commission (in the case of any Major European Markets other than the United Kingdom) or the MHRA (in the case of the United Kingdom) and (b) Pricing Approvals for such Licensed Product for such Indication in such Major European Markets, by the European Commission (in the case of any Major European Markets other than the United Kingdom) or the MHRA (in the case of the United Kingdom).

1.38 "Excluded Compounds" means [***].

1.39 "Existing IND" means the IND for the conduct of the Eisai Ongoing Clinical Trial as more particularly identified on Schedule 1.39.

1.40 "Field" means the prevention, treatment or diagnosis of any indications in humans and animals.

1.41 "First Commercial Sale" means, with respect to a Licensed Product and country, the first sale to a Third Party of such Licensed Product in such country after Regulatory Approval has been obtained in such country to market and sell such Licensed Product. For purposes of clarity, First Commercial Sale excludes (a) any sale to an Affiliate or Sublicensee unless the Affiliate or Sublicensee is the last entity in the distribution chain of the Licensed Product; and (b) any sale or other distribution of a Licensed Product for use in a Clinical Trial or for other Development activity or for any compassionate or named-patient use to the extent sold or distributed at or below the selling Party's manufacturing costs for such Licensed Product.

1.42 "GCP" means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, as set forth in (a) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the "ICH Guidelines") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004), as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, and (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), each as may be amended from time to time.

1.43 "Generic Launch Quarter" means, with respect to a Generic Product in a country or geographic region in the Territory, the Calendar Quarter in which the first commercial sale of the applicable Generic Product in such country or geographic region occurs following receipt of all necessary Regulatory Approvals from the applicable Regulatory Authorities in such country or region to market and sell such Generic Product in such country or geographic region

1.44 "Generic Product" means, with respect to a particular Licensed Product in a country, a pharmaceutical product sold by a Third Party that (a) contains the same active ingredient(s) as such Licensed Product, (b) is determined to be bioequivalent to such Licensed Product in accordance with Applicable Law, and (c) is approved for use in such country pursuant to an expedited regulatory approval process governing approval of generic products based on the then-current standards for regulatory approval in such country and where such regulatory approval was based in significant part upon clinical data generated by a Party (or the Parties) hereunder.

1.45 "GLP" means the applicable then-current good laboratory practice standards as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including in the United States, those promulgated or endorsed by the FDA in U.S. 21 C.F.R. Part 58, or the equivalent thereof as promulgated or endorsed by the applicable Regulatory Authorities outside of the United States.

1.46 "GMP" means all applicable then-current good manufacturing practice standards for fine chemicals, intermediates, bulk products, or finished pharmaceutical products, as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including, as applicable: (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211; (b) all applicable requirements detailed in the EMA's "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products;" and (c) all Applicable Law promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical product, as applicable.

1.47 "GPV" means all applicable then-current good pharmacovigilance practice standards as required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction.

1.48 "Governmental Authority" means any: (a) federal, state, local, municipal, foreign, or other government; (b) governmental or quasi-governmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, and any court or other tribunal); (c) multinational governmental organization or body; or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature.

1.49 "ICH" means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

1.50 "IND" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any amendments thereto. For clarity, references herein to an IND shall include, to the extent applicable, any comparable filing(s) outside the United States for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU).

1.51 "Indication" means an entirely separate and distinct disease or medical condition in humans for which a biopharmaceutical product: (a) that is in a Clinical Trial is intended to treat in such Clinical Trial or (b) has received a separate and distinct Regulatory Approval with an approved label claim to treat such disease or condition, as applicable. For clarity, distinctions between human indications, diseases or conditions with respect to the Licensed Product shall be made by reference to the World Health Organization International Classification of Diseases, version 10 (as revised and updated, the "ICD10").

1.52 "Initiation" means [***].

1.53 "Invention" means any Know-How (including any new and useful process, method of manufacture, chemical composition or composition of matter or biomarker, or any new and useful improvement thereof), whether or not patentable, that is first conceived or reduced to practice (actually or constructively) during the Term, by or on behalf of either Party, or jointly by the Parties, in connection with the Development, Manufacture or Commercialization of the Licensed Compound or any Licensed Product pursuant to this Agreement.

1.54 "Japan Regulatory Approval" means, with respect to a Licensed Product in an Indication, Regulatory Approval (including Pricing Approvals) by the Regulatory Authority in Japan of such Licensed Product for such Indication.

1.55 "Joint Invention" means any Invention, other than Eisai Product Know-How, that is conceived or reduced to practice jointly by any employee, agent or independent contractor of Eisai or its Affiliates and any employee, agent or independent contractor of Pharmavant or its Affiliates.

1.56 "Joint IP" means, collectively, the Joint Inventions and the Joint Patents.

1.57 "Joint Patent" means any Patent, other than Eisai Product Patents, that claims a Joint Invention.

1.58 "Know-How" means algorithms, data, information, inventions, knowledge, methods (including methods of use or administration or dosing), practices, results, software, techniques, technology, know-how and trade secrets, including analytical and quality control data, analytical methods (including applicable reference standards), assays, batch records, chemical structures and formulations, compositions of matter, formulae, manufacturing processes and data, pharmacological, toxicological and clinical test data and results, processes, reports, research data, research tools, sequences, standard operating procedures, and techniques, in each case, whether patentable or not, and, in each case, tangible manifestations thereof.

1.59 "Licensed Compound" means (a) the proprietary compound of Eisai designated as H3B-8800 and described more fully on Schedule 1.59 attached hereto [***].

1.60 "Licensed Product" means any product that constitutes, incorporates, comprises or contains the Licensed Compound, whether or not as the sole active ingredient, in all forms, presentations, and formulations (including manner of delivery and dosage). [***].

1.61 "Loss of Market Exclusivity" means a condition pursuant to which, with respect to a particular Licensed Product in a particular country or region: (a) one or more Generic Products are being marketed or sold in such country or region by a Third Party and (b) such Generic Products, by unit equivalent volume, in any [***] following the [***], exceed [***] of the aggregate market share of the Generic Products and Licensed Product based on data provided by [***], [***] or other comparable firm reasonably acceptable to the Parties (the "Royalty Reduction Trigger"); provided, that, if in any [***] following the Royalty Reduction Trigger date, the Generic Products, by unit equivalent volume fall to below [***] of the aggregate market share of the Generic Products and Licensed Product (determined as provided above), then the condition of Loss of Market Exclusivity will cease with respect to such Licensed Product in such country or region unless and until the Royalty Reduction Trigger occurs again with respect thereto.

1.62 "MA" or "Marketing Authorization" means an MAA that has been approved by the applicable Governmental Authority to market the applicable pharmaceutical product in a country or group of countries.

1.63 "MAA" means a Marketing Authorization Application or similar application, as applicable, and all amendments and supplements thereto, submitted to the FDA, EMA, or any equivalent filing in a country or regulatory jurisdiction other than the United States or EU with the applicable Regulatory Authority, to obtain marketing approval for a pharmaceutical product, in a country or in a group of countries.

1.64 "Major European Markets" means [***].

1.65 Major Market" means [***].

1.66 "Manufacture" means all activities related to the manufacture of the Licensed Compound or any Licensed Product or any raw materials thereof, including (a) manufacturing process development and validation, process improvements, associated analytical development and validation, and the manufacture and testing of stability or consistency lots; and (b) manufacturing a product or compound for the Development or Commercialization, including labelling and packaging, of the Licensed Compound or any Licensed Product, including both in-process and as a finished product or for any compound testing, quality assurance activities related to manufacturing and release of such Licensed Compound or Licensed Product, ongoing stability tests, and regulatory activities related to any of the foregoing.

1.67 "Medical Affairs Activities" means the design, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or support or conduct Clinical Trials regarding, the Licensed Product, including: (a) the activities to be conducted by Medical Liaisons; (b) sponsoring, or the obtaining of grants to support, continuing independent medical education (including independent symposia and congresses); (c) participation in international congresses and (d) the development, publication and dissemination of scientific and clinical information in support of an approved Indication for the Licensed Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing representatives of or received by letter, phone call or email or other means of communication by Pharmavant, its Affiliates or its Sublicensees.

1.68 "Medical Liaisons" means the health care professionals employed or engaged by Pharmavant, its Affiliates or its Sublicensees with sufficient health care experience to engage in in-depth scientific dialogue with physicians regarding medical issues or relevant scientific topics associated with the Licensed Product and are not sales representatives or otherwise engaged in direct selling or promotion of the Licensed Product.

1.69 "Milestone Event" means, as applicable, a Development Milestone Event, a Regulatory Milestone Event or a Commercialization Milestone Event.

1.70 "Milestone Payment" means, as applicable, a Development Milestone Payment, a Regulatory Milestone Payment or a Commercialization Milestone Payment.

1.71 "NDA" means a New Drug Application submitted to the FDA, or any successor application or procedure, as more fully defined in 21 C.F.R. § 314.50 et. seq.

1.72 "Net Sales" means [***].

1.73 “Paragraph IV Certification” means, with respect to a Licensed Product, the certification filed against the Licensed Product with the FDA under and pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) and 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

1.74 “Patents” means(a) all patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, converted provisionals, and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications in (a) and (b), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, reissues, reexaminations and extensions (including any supplementary protection certificates) of the foregoing patents or patent applications in (a), (b) and (c); and (e) any similar rights, including registration patent or patents of addition to any of such foregoing patent applications and patents.

1.75 “PMDA” means the Pharmaceuticals and Medical Devices Agency, which is the Governmental Authority in Japan in charge of reviewing drugs and medical devices, overseeing post-marketing safety issues and providing relief for adverse health effects.

1.76 “Person” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.77 “Personal Data” means (a) all information identifying, or in combination with other information, identifiable to, an individual, including pseudonymized (key-coded) Clinical Data containing such information; and (b) any other information that is governed, regulated or protected by one or more Data Security and Privacy Laws.

1.78 “Pharmavant Background Know-How” means any Know-How that (a) is Controlled by Pharmavant or any of its Affiliates as of the Effective Date or (b) becomes Controlled by Pharmavant during the Term outside of the conduct of Development, Manufacture or Commercialization activities with respect to the Licensed Compound or the Licensed Products which, in either case, (i) encompasses or relates to the Licensed Compound or any Licensed Product or (ii) is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory.

1.79 “Pharmavant Background Patents” means any Patents that (a) are Controlled by Pharmavant or any of its Affiliates as of the Effective Date or (b) become Controlled by Pharmavant during the Term outside of the conduct of Development, Manufacture or Commercialization activities with respect to the Licensed Compound or the Licensed Products and that, in either case, claim any Pharmavant Background Know-How.

1.80 "Pharmavant Invention" means any Invention, other than Eisai Product Know-How, that is conceived or reduced to practice solely by any employee, agent or independent contractor of Pharmavant or its Affiliates, including any such Invention that is directed to a formulation, product by process, method of use or treatment, manufacture, preparation or administration or biomarker not solely directed to the Licensed Compound or Licensed Product.

1.81 "Pharmavant Invention Patents" means any Patents, other than Eisai Product Patents, that are Controlled by Pharmavant during the Term that claim Pharmavant Inventions.

1.82 "Pharmavant IP" means, collectively, the Pharmavant Background Patents, the Pharmavant Background Know-How, the Pharmavant Inventions and the Pharmavant Invention Patents.

1.83 "Pharmavant Patents" means, collectively, the Pharmavant Background Patents and the Pharmavant Invention Patents.

1.84 "Phase 1 Clinical Trial" means a Clinical Trial of a Licensed Product on a sufficient numbers of normal volunteers and/or patients that is designed to establish that such Licensed Product is safe for its intended use and to support its continued testing in Phase 2 Clinical Trials, as further defined in Federal Regulation 21 C.F.R. §312.21(a) and its foreign equivalents.

1.85 "Phase 2 Clinical Trial" means a Clinical Trial of a Licensed Product, including a separate Clinical Trial or the second part of a fused "Phase 1/2" trial, in which either such separate Clinical Trial or second part of such fused "Phase 1/2" trial utilizes the pharmacokinetic and pharmacodynamic information obtained from one or more previously conducted Phase 1 Clinical Trials that are designed to provide a preliminary determination of efficacy or an appropriate dose of such Licensed Product in the target patient population as further defined in Federal Regulation 21 C.F.R. §312.21(b) and its foreign equivalents.

1.86 "Phase 3 Clinical Trial" means a pivotal Clinical Trial in humans of the efficacy and safety of a Licensed Product, which is prospectively designed to demonstrate statistically whether such Licensed Product if effective and safe for use in a particular Indication in a manner sufficient to file an NDA or MAA to obtain regulatory approval to market the Licensed Product, as further defined in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents, and that is registered with FDA (or its foreign equivalents) as a Phase 3 Clinical Trial.

1.87 "Pricing Approval" means any approval, agreement, determination, or decision establishing prices that can be charged to consumers for a pharmaceutical product or that will be reimbursed by Governmental Authorities or other payers for a biopharmaceutical product, in each case, in a country where Governmental Authorities approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.88 [***].

1.89 "Processing" (or its conjugates) means any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.90 "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent, the preparation, filing, prosecution, and maintenance of such Patent, as well as re-examinations, reissues, appeals, and requests for patent term adjustments, patent term extensions and Supplemental Protection Certificates with respect to such Patent, together with the initiation or defense of interferences, oppositions, post grant review, inter partes review, derivations, re-examinations, post-grant proceedings, and other similar proceedings (or other defense proceedings with respect to such Patent, but excluding the defense of challenges to such Patent as a counterclaim in an infringement proceeding) with respect to the particular Patent, and any appeals therefrom.

1.91 "Public Official" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

1.92 "Regulatory Approval" means with respect to a country, geographic region, extra-national territory, province, state or other regulatory jurisdiction, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell, manufacture, import, export or market a Licensed Product in such country, geographic region, extra-national territory, province, state or other regulatory jurisdiction (whether as an initial or accelerated approval or for a label expansion that was already approved), and including, where applicable, (a) any Pricing Approvals, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approvals.

1.93 "Regulatory Authority" means any national or supranational Governmental Authority, including the U.S. Food and Drug Administration (and any successor entity thereto) (the "FDA") in the United States, the European Medicines Agency (and any successor entity thereto) (the "EMA") or the European Commission (and any successor entity thereto), as applicable, in the EU, and the Ministry of Health, Labour, and Welfare (the "MHLW") or the PMDA (or any successor to either of them) as the case may be in Japan, the Medicines and Healthcare Products Regulatory Agency (the "MHRA") in the United Kingdom, or any health regulatory authority in any country that is a counterpart to the foregoing agencies, in each case, that holds responsibility for development and commercialization of, and the granting of Regulatory Approval for, a pharmaceutical product in such country.

1.94 "Regulatory Exclusivity" means, with respect to a particular Licensed Product in a country in the Territory, any exclusive marketing rights or data protection (including for clarity new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity) conferred by the Regulatory Authority in such country which confers an exclusive commercialization period during which Pharmavant, its Affiliates or Sublicensees have the exclusive right to market and sell such Licensed Product in such country and excludes the Commercialization of a Generic Product, excluding any rights conferred by or based on any Patents.

1.95 "Regulatory Filing" means any filing with any Regulatory Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Licensed Product.

1.96 "Regulatory Materials" means the regulatory registrations, applications, authorizations, and approvals (including MAs, supplements and amendments, pre- and post-approvals, Pricing Approvals, and labeling approvals), Regulatory Filings, Regulatory Approvals, and other submissions made to or with, and minutes of meetings with, any Regulatory Authority for the research, development (including the conduct of Clinical Trials), manufacture, or commercialization of a pharmaceutical product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents, referenced in the complete regulatory chronology for each such submission including all drug master files (if any), INDs and NDAs, and foreign equivalents of any of the foregoing.

1.97 "Regulatory Transition Plan" means the written plan which will set forth the Regulatory Transition Activities to be conducted by Eisai and Pharmavant pursuant to Section 3.2.3, as such written plan may be amended, modified or updated from time-to-time in accordance with the terms of this Agreement.

1.98 "Related Party" means, with respect to a Licensed Product, Pharmavant's Affiliates and its and their respective Sublicensees (and such Sublicensees' affiliates), in each case, that sells such Licensed Product. For clarity, the term Related Party does not include any distributors or wholesalers of Pharmavant unless any such entity is an Affiliate of Pharmavant.

1.99 "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period of time commencing on the First Commercial Sale of such Licensed Product in such country and expiring upon the latest of: (a) the expiration of the last Valid Claim within the Eisai Product Patents, Eisai Patents or Joint Patents which Covers such Licensed Compound or Licensed Product in such country; (b) the ten (10) year anniversary of the date of First Commercial Sale of the first Licensed Product in such country; and (c) the expiration of the last-to-expire Regulatory Exclusivity with respect to such Licensed Product in such country.

1.100 "Share Price" means [***].

1.101 "Sublicensee" means, with respect to Pharmavant, a Third Party to which Pharmavant has granted a sublicense, either directly or indirectly, under Eisai Product Patents, the Eisai Product Know-How and the Eisai IP licensed to Pharmavant by Eisai pursuant to this Agreement, to Develop, Manufacture or Commercialize Licensed Products in the Field in the Territory, but excluding: (a) any Third Party acting as a distributor or to which specific limited activities have been delegated; and (b) Eisai and any of its Affiliates.

1.102 "Tax" means any direct or indirect tax, excise or duty and any surcharge thereon levied by any Governmental Authority in accordance with Applicable Law.

1.103 "Terminated Product" means, with respect to a given Licensed Product with respect to which this Agreement is terminated in accordance with Article 10, the form as such Licensed Product exists as of the effective date of termination.

1.104 Terminated Territory" means, with respect to a given Licensed Product, any country or other jurisdiction with respect to which this Agreement is terminated in accordance with Article 10. In the event of termination of this Agreement in its entirety with respect to such Licensed Product, all countries and jurisdictions in the Territory will be Terminated Territories.

1.105 "Territory" means all countries and territories of the world.

1.106 "Third Party" means any Person, other than Eisai or Pharmavant, that is not an Affiliate of Eisai or of Pharmavant.

1.107 "Third Party Claim" means any and all suits, claims, actions, proceedings, or demands brought by a Third Party.

1.108 "United States" or "U.S." means the United States of America and all of its territories and possessions.

1.109 "U.S. Regulatory Approval" means, with respect to a Licensed Product and a given Indication, Regulatory Approval by the FDA of such Licensed Product for that Indication.

1.110 "Valid Claim" means (a) a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), or (b) [***].

1.111 Additional Definitions. Each of the following terms has the meanings described in the corresponding section of this Agreement indicated below:

Agreement	Preamble
Commercialization Milestone Event	Section 5.2.3(a)
Commercialization Milestone Payment	Section5.2.3(a)
[***]	[***]
Cure Period	Section 10.2.1
Developing	Section 1.23
Development	Section 1.24
Development Milestone Event	Section 5.2.1(a)
Development Milestone Event Notice	Section 5.2.1(a)
Development Milestone Payment	Section 5.2.1(a)
Development Plan	Section 3.1.2
Disclosing Party	Section 7.1
Dispute	Section 11.6.2(a)
EEA	Section 8.4.1(b)
Effective Date	Preamble
Eisai	Preamble
Eisai Indemnitees	Section 9.1
Eisai Transition Plan	Section 10.6.1(d)
Electronic Delivery	Section 11.17
EMA	Section 1.94
Executive Officer	Section 3.4.3
Existing Drug Substance Inventory	Section 4.3.1(a)
Existing Raw Materials Inventory	Section 4.3.1(b)
Existing Transferred Inventory	Section 4.3.1(a)
Existing Regulatory Materials	Section 3.2.3(a)
FDA	Section 1.94
GAAP	Section 1.1
[***]	[***]
IAS/IFRS	Section 1.1
ICC	Section 11.6.2(b)
ICD10	Section 1.51
ICH Guidelines	Section 1.42
Indemnification Claim Notice	Section 9.3.1
Indemnitee	Section 9.3.1
Indemnitor	Section 9.3.1
Infringement	Section 6.3.1
Insolvency Event	Section 10.4.1
[***]	[***]
Manufacturing Know-How and Materials	Section 4.4.1
Manufacturing Technology Transfer	Section 4.4.1
Manufacturing Technology Transfer Plan	Section 4.4.1

MHLW	Section 1.94
MHRA	Section 1.94
Parties	Preamble
Party	Preamble
Patent Term Restoration	Section 6.3.10
Receiving Party	Section 7.1
Regulatory Milestone Event	Section 5.2.2
Regulatory Milestone Payment	Section 5.2.2
Regulatory Transition Activities	Section 3.2.3(b)
Royalty Reduction Trigger	Section 1.61
Pharmavant	Preamble
Pharmavant Indemnitees	Section 9.2
Pharmavant Manufacturing Know-How	Section 10.6.1(d)(ix)
Roivant Sciences	Recitals
Pharmavant Trademarks	Section 6.6
Securities Regulators	Section 7.3.1(a)
Share Purchase Agreement	Section 5.1(b)
Tactical Plan	Section 1.16
Term	Section 10.1.1
Third Party Infringement	Section 6.5.1
Transferred Regulatory Materials	Section 3.2.3(b)
Transitional Supply Agreement	Section 4.3.2

ARTICLE 2
GRANT OF RIGHTS AND LICENSES

2.1 License Grants to Pharmavant.

2.1.1 Grant of Exclusive License. Subject to the terms and conditions of this Agreement, Eisai hereby grants to Pharmavant and its Affiliates an exclusive (even as to Eisai and its Affiliates, but subject to Eisai's retained rights set forth in Section 2.3 below) license, with the right to grant sublicenses in accordance with Section 2.1.3, under the Eisai Product Patents and Eisai Product Know-How, to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory.

2.1.2 Grant of Non-Exclusive License. Subject to the terms and conditions of this Agreement, Eisai hereby grants to Pharmavant and its Affiliates a non-exclusive license, with the right to grant sublicenses in accordance with Section 2.1.3, under the Eisai IP, to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory.

2.1.3 Right to Sublicense. Pharmavant shall have the right to grant sublicenses under the licenses granted to it in Section 2.1.1 and Section 2.1.2 through multiple tiers of sublicensees: (a) subject to Section 2.2, to contract research organizations, contract manufacturing organizations, distributors and other Third Party subcontractors for the sole purpose of performing Pharmavant's obligations hereunder with respect to the Development, Manufacture and

Commercialization of the Licensed Compound and the Licensed Products in the Field in the Territory; and (b) to any Sublicensee with respect to the Development, Manufacture and/or Commercialization of the Licensed Product in the Field and in the Territory. In connection with any sublicense agreement entered into by Pharmavant pursuant to this Section 2.1.3, (i) Pharmavant shall ensure that each of its Sublicensees is bound by a written agreement that is consistent with, and subject to the terms and conditions of, this Agreement; (ii) Pharmavant shall be responsible for the performance of any of its Sublicensees that are exercising rights under a sublicense of the license granted to it in Section 2.1.1 and/or Section 2.1.2, and the grant of any such sublicense shall not relieve Pharmavant of its obligations under this Agreement, except to the extent they are satisfactorily performed by any such Sublicensee(s); and (iii) no later than [***] following the execution of each sublicense with a Sublicensee for the Development, Manufacture or Commercialization of any Licensed Product in the Territory as provided in this Section 2.1.3, Pharmavant shall provide Eisai with a redacted copy of such sublicense agreement as executed; provided, that, such copy may be redacted to remove provisions that are not necessary to monitor compliance with this Section 2.1.3; and provided, further, that no such copy need be shared for a sublicense agreement entered into by Pharmavant with any entity listed in clause (a) above. In the event of any material breach by any such Sublicensee of any sublicense agreement entered into by Pharmavant pursuant to this Section 2.1.3 that would be a material breach of this Agreement by Pharmavant, Pharmavant shall promptly terminate such sublicense agreement if such breach is not cured within [***] of Pharmavant becoming aware of such breach.

2.2 Subcontracting. Pharmavant may subcontract to Third Parties the performance of tasks and obligations related to Pharmavant's Development, Manufacture and Commercialization of the Licensed Compound and any Licensed Products under this Agreement as Pharmavant deems appropriate, which subcontract may include a sublicense of rights necessary for the performance of the subcontract as reasonably required; provided, that Pharmavant shall remain responsible for the performance of this Agreement and shall cause any such subcontractor to comply with all applicable terms and conditions of this Agreement.

2.3 Eisai Retained Rights. Notwithstanding the foregoing, Eisai hereby retains the right under Eisai Product Know-How and Eisai Product Patents to (a) conduct the Eisai Ongoing Clinical Trial until the transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan in accordance with Section 3.2.3(b) and (b) Manufacture the Licensed Compound in the Territory solely for use (i) by Pharmavant for clinical Development in the Field and in the Territory pursuant to Section 4.3.2 and (ii) by Eisai to conduct the Eisai Ongoing Clinical Trial until the transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan in accordance with Section 3.2.3(b), in each case, whether directly or through its Affiliates or Third Party contractors.

2.4 [***]

2.5 No Other Rights. Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by a Party to the other Party. All rights with respect to Patents, Know-How or other intellectual property rights that are not specifically granted herein are reserved to the owner thereof. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license, or other right in or to any Patents, Know-How, or other intellectual property rights of the other Party, including tangible or intangible items owned, controlled, or developed by the other Party, or provided by the other Party to the receiving Party at any time, in each case, pursuant to this Agreement.

ARTICLE 3
DEVELOPMENT ACTIVITIES; REGULATORY ACTIVITIES; COMMERCIALIZATION

3.1 Development Activities.

3.1.1 In General. Subject to the terms and conditions of this Agreement, including Section 3.4.2, and, except with respect to the conduct by Eisai of the Eisai Ongoing Clinical Trial pursuant to Section 3.1.3, Pharmavant shall have the sole right and responsibility and sole authority, itself or with or through its Affiliates, Sublicensees, or other Third Parties, [***], to Develop the Licensed Compound and Licensed Products in the Field in the Territory in accordance with the Development Plan. On and after the Effective Date, subject to the terms and conditions of this Agreement,[***] associated with the Development of the Licensed Compound and Licensed Products in the Field in the Territory.

3.1.2 Development Plan. The Development of the Licensed Compound and Licensed Products by Pharmavant, its Affiliates or its Sublicensees in the Territory will be governed by a written development plan covering the Development of the Licensed Compound and the Licensed Products, and regulatory strategy for the Licensed Products, by Indication and

by individual countries or geographic regions in the Territory (each such plan, as updated from time-to-time in accordance with the terms of this Agreement, a "Development Plan"). Commencing on the date of transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan and continuing for the remainder of the Term, Pharmavant may make any amendment to the Development Plan at any time, [***].

3.1.3 Conduct of Eisai Ongoing Clinical Trial. Until the date of transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan in accordance with Section 3.2.3(b), Eisai shall be responsible for the conduct of the Eisai Ongoing Clinical Trial in accordance with the protocol set forth in the Initial Development Plan. For the avoidance of doubt, [***] associated with the conduct of the Eisai Ongoing Clinical Trial on and after the Effective Date shall be borne by [***], and [***] on and after the Effective Date and until the date of such transfer, for which [***] delivers an invoice, together with reasonable supporting documentation, to [***] within [***] after the end of [***] in which they were incurred. On and after the date of transfer sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan in accordance with Section 3.2.3(b), Pharmavant shall be responsible,[***], for the conduct of the Eisai Ongoing Clinical Trial in accordance with the protocol set forth in the Initial Development Plan or the Development Plan in effect at such time, as applicable.

3.1.4 Use of Third Parties. Pharmavant may retain one or more Third Parties to conduct Development activities with respect to the Licensed Compound and any Licensed Products in the Field in the Territory, subject to the terms of this Agreement. Any Third Parties conducting such Development activities shall be subject to (a) an obligation to assign or exclusively license back all intellectual property, whether or not patentable, to Pharmavant generated in the conduct of such activities (other than intellectual property solely related to improvements to any such Third Party's background technology that would not be infringed or misappropriated by the Development, Manufacture or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory) and (b) confidentiality and non-use obligations consistent with those set forth in this Agreement; provided, that, the term of such Third Party's obligations regarding confidentiality and non-use may be limited to [***] after the date of disclosure to such Third Party. Pharmavant shall remain responsible and liable for the performance by its Affiliates or permitted Third Party contractors of any of its obligations under this Agreement that it delegates to any such Third Party contractor.

3.1.5 Development Diligence. Subject to the terms and conditions of this Agreement, Pharmavant, itself or with or through its Affiliates, Sublicensees, or other Third Parties, shall use Commercially Reasonable Efforts to (a) Develop the Licensed Compound in at least one Major Market and (b) seek and obtain Regulatory Approvals for a Licensed Product in at least one Major Market.

3.1.6 Standards of Conduct. Pharmavant shall perform, and shall ensure that its Affiliates perform, and shall cause its Sublicensees and Third Party contractors to perform, its Development activities with respect to the Licensed Compound and the Licensed Products in good scientific manner, and in compliance with the requirements of Applicable Law, including GLP, GCP, GMP, GPV and part 11 of Title 21 of the Code of Federal Regulations (Electronic Systems and Data Integrity) (21 CFR Part 11) to the extent applicable (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any applicable country).

3.1.7 Development Records. Pharmavant shall maintain and shall cause its Affiliates, Sublicensees and Third Party contractors to maintain reasonably complete and accurate records regarding its Development of the Licensed Compound and Licensed Products in the Field in the Territory in accordance with GLP, GMP, GCP, GPV, and part 11 of Title 21 of the C ode of Federal Regulations (Electronic Systems and Data Integrity) (21 CFR Part 11) as applicable, and in compliance with other Applicable Law. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Compound and Licensed Products in good scientific manner appropriate for regulatory and patent purposes.

3.1.8 Development Updates. Pharmavant shall submit [***] a written report summarizing all material Development activities with respect to the Licensed Compound and Licensed Products pursuant to this Agreement since Pharmavant's delivery of the prior report which shall include reasonable detail regarding the status of all preclinical IND-enabling studies and activities (including toxicology and pharmacokinetic studies), Clinical Trials, Manufacturing and other Development activities conducted under this Agreement: (a) during Calendar Year 2022, [***], and (b) commencing with Calendar Year 2023 and continuing thereafter,[***]. Such report shall contain sufficient detail to enable Eisai to assess Pharmavant's compliance with its Development obligations under Section 3.1.5.

3.2 Regulatory Matters.

3.2.1 Responsibility. Subject to the terms and conditions of this Agreement, including Section 3.4.2, (a) Pharmavant shall have the sole responsibility and sole authority with respect to all regulatory matters applicable to the Licensed Compound or any Licensed Products in the Territory in accordance with the Development Plan and Commercialization Plan, including the content of any regulatory filing or dossier, pharmacovigilance reporting, labeling, safety, and the decision to file or withdraw any MAA or to cease or suspend any Clinical Trial, or to recall or withdraw any Licensed Product and (b) Pharmavant shall have sole responsibility,[***], for preparing and submitting all Regulatory Materials for Licensed Products in the Field in the Territory, including the responsibility for preparing, submitting and holding all INDs, NDAs and MAAs for Licensed Products in the Territory. Pharmavant will own all Regulatory Materials for Licensed Products and all such Regulatory Materials shall be submitted in the name of Pharmavant (or its Affiliate or Sublicensee, as applicable). For clarity, this Section 3.2.1 shall not be deemed to transfer ownership of any Know-How provided by Eisai to Pharmavant for use in preparing and submitting such Regulatory Materials. [***]

3.2.2 Eisai Ongoing Clinical Trial. Notwithstanding the foregoing and except as set forth in the Development Plan, until the transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant pursuant to the Regulatory Transition Plan in accordance with Section 3.2.3(b), Eisai shall be responsible for any communications and interactions with Regulatory Authorities with respect to the Eisai Ongoing Clinical Trial in accordance with the Development Plan; provided, that, Eisai shall previously have consulted and coordinated with and shall implement all comments received from Pharmavant with respect thereto.

3.2.3 Regulatory Materials.

(a) Existing Regulatory Materials. Prior to the transfer of all Regulatory Materials for the Licensed Compound held or filed by or on behalf of Eisai or its Affiliates prior to the Effective Date (the "Existing Regulatory Materials") in accordance with the Regulatory Transition Plan, Eisai (or its designee) shall have the right to file, maintain, and hold title to such Existing Regulatory Materials; provided, that, with respect to any such filings and maintenance, Eisai shall previously have consulted and coordinated with and shall implement all comments received from Pharmavant with respect thereto.

(b) Regulatory Transition Plan and Regulatory Transition Activities. Eisai shall (a) as promptly as possible following the Effective Date and in accordance with the timeline set forth in the Regulatory Transition Plan, assign and transfer to Pharmavant (or its designee) sponsorship and control of the Eisai Ongoing Clinical Trial and (b) assign and transfer to Pharmavant, within the timelines specified in the Regulatory Transition Plan, any and all Regulatory Materials, including the Existing IND, for or in respect of the Licensed Compound in the Territory held or filed by or on behalf of Eisai or its Affiliates prior to or after the Effective Date (the "Transferred Regulatory Materials"), by undertaking the steps described in the Regulatory Transition Plan within the timelines set forth in the Regulatory Transition Plan (the "Regulatory Transition Activities"); provided, further, that, such Regulatory Transition Activities shall be subject to any obligations of Eisai under Applicable Law. Unless otherwise required by Applicable Law, from and after such assignment and transfer, Pharmavant (or its designee) shall have the sole right, [***], to (i) conduct the Eisai Ongoing Clinical Trial in accordance with the Development Plan and (ii) file, maintain, and hold title to all Transferred Regulatory Materials in accordance with the Development Plan and the Commercialization Plan. As promptly as practicable following the Effective Date, but no later than [***] from the Effective Date, the Parties shall cooperate reasonably in good faith to agree on the Regulatory Transition Plan and to make arrangements to allow for the completion of the Regulatory Transition Activities as promptly as practicable after the Effective Date. The preliminary Regulatory Transition Plan is attached as Exhibit C, the details of which shall be subject to review and approval by Eisai.

3.2.4 Right of Reference; Access to Data.

(a) Pharmavant Right of Reference. Until the date on which the Existing Regulatory Materials have been transferred and assigned to Pharmavant or its designee, Pharmavant and its designees shall have, and Eisai (on behalf of itself and its Affiliates) hereby grants to Pharmavant and its designees, access and a right of reference (without any further action required on the part of Eisai or its Affiliates, whose authorization to file this consent with any Regulatory Authority is hereby granted) to all such Existing Regulatory Materials and all data contained or referenced in any such Existing Regulatory Materials for Pharmavant and its designees to exercise its rights and perform its obligations under this Agreement. Pharmavant and its designees shall have access to all data contained or referenced in any such Existing Regulatory Materials in order to exercise such access and right of reference, and Eisai shall ensure that Pharmavant and its designees are afforded such access. Eisai shall provide or submit any written consents or notices as may be required in order for Pharmavant to exercise such rights contemplated in this Section 3.2.4(a).

(b) Eisai Right of Reference. Eisai and its designees shall have, and Pharmavant (on behalf of itself and its Affiliates) hereby grants to Eisai and its designees, access and a right of reference (without any further action required on the part of Pharmavant or its Affiliates, whose authorization to file this consent with any Regulatory Authority is hereby granted) to all Regulatory Materials Controlled by Pharmavant with respect to the Licensed Compound and the Licensed Product and all data contained or referenced in any such Regulatory Materials, for Eisai and its designees to the extent necessary to perform its obligations under this Agreement. Eisai and its designees shall have access to all data contained or referenced in any such Regulatory Materials in order to exercise such access and right of reference to the extent necessary to comply with this Agreement, and Pharmavant shall ensure that Eisai and its designees are afforded such access to the extent necessary to comply with this Agreement. Pharmavant shall provide or submit any written consents or notices as may be required in order for Eisai to exercise such rights contemplated in this Section 3.2.4(b).

3.3 Commercialization.

3.3.1 Pharmavant Responsibilities. Subject to the terms and conditions of this Agreement, including Section 3.4.2, Pharmavant shall have the sole right and sole authority, at [***] and itself or with or through its Affiliates, Sublicensees, to Commercialize the Licensed Products in the Field in the Territory in accordance with the Commercialization Plan, including the sole right, at [***], itself or with or through its Affiliates, Sublicensees, or other Third Parties, to, in accordance with the Commercialization Plan, (a) conduct Medical Affairs Activities with respect to the Licensed Products in the Field in the Territory, (b) book all sales of the Licensed Products in the Territory, (c) develop and implement the brand and commercial strategy to be used for the Licensed Products in the Territory, (d) make all pricing determinations with respect to the Licensed Product in the Territory and (e) conduct all marketing, promotion and sales activities for the Licensed Products in the Territory. Pharmavant may make any amendment to the Commercialization Plan at any time; [***].

3.3.2 Diligence. Pharmavant will use Commercially Reasonable Efforts to Commercialize a Licensed Product in accordance with the Commercialization Plan in each country in the Territory in which Pharmavant receives Regulatory Approval for such Licensed Product in the Indications for which it receives Regulatory Approval for such Licensed Product in such country.

3.3.3 Reports. Following the first Regulatory Approval of a Licensed Product in any country in the Territory, Pharmavant shall provide [***] a written report not less [***] that summarizes the Commercialization activities on a Licensed Product-by-Licensed Product basis conducted by Pharmavant, and its Affiliates and Sublicensees in the Territory since the date of the prior report by Pharmavant. Such report shall contain sufficient detail to enable Eisai to assess Pharmavant's compliance with its Commercialization obligations in Section 3.3.2. In addition, Pharmavant shall have a meeting in person, by videoconference, teleconference or other similar communications equipment not less than [***] to update Eisai as to the status of Pharmavant's Commercialization activities.

3.3.4 Compliance. Pharmavant will conduct all Commercialization activities with respect to the Licensed Products in good scientific manner, and in compliance with Applicable Law, including GLP, GCP, GMP or GPV to the extent applicable (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any country in the Territory).

3.4 [***].

3.4.1 [***]

(a) [***].

3.4.2 [***].

3.4.3 [***].

3.4.4 [***].

3.4.5 [***].

3.4.6 [***].

3.4.7 [***].

ARTICLE 4
ASSISTANCE; DISCLOSURE OF KNOW-HOW; TECHNOLOGY TRANSFER; MANUFACTURING

4.1 Disclosure of Eisai Product Know-How and Eisai Background Know-How. As soon as reasonably practicable and in any event within[***] of the Effective Date and thereafter during the Term as may be reasonably requested by Pharmavant from time to time, Eisai shall disclose to Pharmavant and its designees, including by providing electronic copies thereof, via a mutually agreeable method of transfer, all Eisai Product Know-How and Eisai Background Know-How (other than Eisai Background Know-How solely relating to the Manufacture of the Licensed Compound, which shall be disclosed to Pharmavant pursuant to Section 4.4) licensed to Pharmavant pursuant to Section 2.1.1 or 2.1.2, including any materials and documentation (including data and protocols) included therein. Eisai shall, and shall cause its Affiliates to, cooperate with Pharmavant and its designees and provide reasonable assistance to Pharmavant for up to [***] after the Effective Date to enable Pharmavant to Develop the Licensed Compound, as and to the extent reasonably requested by Pharmavant and agreed to by Eisai, including by: (a) providing Pharmavant with such assistance as may be reasonably requested by Pharmavant with respect to Development transition matters related to the Licensed Compound; and (b) providing Pharmavant with such access as may be reasonably requested by Pharmavant, by teleconference or in-person to Eisai personnel (and personnel of its Affiliates) involved in the Development of the Licensed Compound to assist with the transition and answer questions related to the Licensed Compound. After the expiration of such [***] period, and for a period of up to [***] from the Effective Date, Pharmavant may request continued reasonable assistance from Eisai, at [***] and Eisai shall use commercially reasonable efforts to provide such reasonable assistance upon Pharmavant's request and to the extent agreed to by Eisai.

4.2 Manufacturing Rights. Subject to the terms and conditions of this Agreement, Pharmavant shall have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, Sublicensees, or other Third Parties, [***], to Manufacture the Licensed Product in the Field for the Territory. Notwithstanding the foregoing, Eisai hereby retains the right to Manufacture the Licensed Compound and the Licensed Products in the Territory solely as provided in Section 4.3, whether directly or through its Affiliates or the Eisai Manufacturer.

4.3 Supply of Licensed Compound and Raw Materials to Pharmavant.

4.3.1 Initial Supply of Existing Drug Substance Inventory and Existing Raw Materials Inventory.

(a) Eisai shall supply to Pharmavant or to any Third Party designee any or all (as and to the extent requested by Pharmavant) quantity of the existing inventory of the Licensed Compound (both drug substance and drug product), including [***] (the "Existing Drug Substance Inventory"), together with all intermediates identified on Schedule 4.3.1(a) attached

hereto (the "Existing Transferred Inventory"), held as of the Effective Date by or on behalf of Eisai or its Affiliates [***]. To the extent that Pharmavant wishes to have any portion of the Existing Transferred Inventory supplied to any Third Party designee other than an Eisai Manufacturer, Pharmavant shall provide Eisai with prior written notice which shall identify such Third Party designee. Notwithstanding the foregoing, Eisai shall have the right to retain such quantities of drug product of the Licensed Compound as may be reasonably necessary for Eisai to continue its activities with respect to the Eisai Ongoing Clinical Trial as contemplated by this Agreement until the transfer of sponsorship and control of the Eisai Ongoing Clinical Trial to Pharmavant in accordance with Section 4.4, after which any remaining amount of such retained quantities will be transferred to Pharmavant.

(b) To the extent requested by Pharmavant, Pharmavant may, in its discretion, purchase from Eisai the quantity of the materials identified on Schedule 4.3.1(b) (the "Existing Raw Materials Inventory"), [***], pursuant to terms of sale mutually agreed by the Parties.

(c) Delivery of the Existing Transferred Inventory and the Existing Raw Materials Inventory supplied by Eisai will be made [***]. [***] shall be responsible for obtaining all licenses or other authorizations for the exportation and importation of such Existing Transferred Inventory and Existing Raw Materials Inventory and [***] shall contract for shipment and insurance of such Existing Transferred Inventory and Existing Raw Materials Inventory from Eisai's or the Eisai Manufacturer's facility, at [***], provided that [***] or its Affiliates shall provide any reasonable assistance requested by [***] in connection with such activities at [***]. [***] shall also be responsible for the clinical packaging, labeling, QC/QA/QP release, storage, customs clearance and distribution of such Existing Transferred Inventory and Existing Raw Materials Inventory, at [***]. Following the Effective Date, the Parties hereby agree to negotiate in good faith and execute a quality agreement as may be needed for quality assurance in connection with the delivery of the Existing Transferred Inventory and the Existing Raw Materials Inventory by Eisai.

4.3.2 Manufacture and Clinical Supply. Pharmavant shall be solely responsible for the Manufacture and supply of the Licensed Compound and all Licensed Products during the Term in the Field for the Territory; provided, that, upon the written request of Pharmavant, the Parties will negotiate in good faith the terms of a transitional supply agreement (the "Transitional Supply Agreement") to have Eisai and/or the Eisai Manufacturers Manufacture and supply to Pharmavant drug product, at [***].

4.3.3 No Additional Supply Obligations. Pharmavant may not at any time during the Term request Eisai to, and Eisai shall have no obligation under this Agreement to, procure or Manufacture any Licensed Compound (drug substance or drug product) for, or for the benefit of, Pharmavant other than the transfer of the Existing Transferred Inventory and the Existing Raw Materials Inventory as provided in this Section 4.3 and pursuant to Section 4.3.2 and the terms of the Transitional Supply Agreement.

4.4 Manufacturing Technology Transfer.

4.4.1 Manufacturing Technology Transfer. Without limiting the other provisions of this Article 4, as soon as reasonably practicable following the Effective Date, Eisai shall transfer (from Eisai or its Affiliates) to Pharmavant and its designees copies (in an electronic format) of all Eisai Product Know-How and Eisai Background Know-How, respectively, solely related to the Manufacture of the Licensed Compound (including drug substance and drug product) (the "Manufacturing Know-How"), [***] (such activities, "Manufacturing Technology Transfer").

4.4.2 Eisai Assistance. At the reasonable request of Pharmavant from time to time, Eisai shall make its sites, employees and consultants (including personnel and sites of its Affiliates) reasonably available to Pharmavant and its Third Party designees for up to [***] after the Effective Date to provide consultation and technical assistance in order to ensure an orderly transition of the Manufacturing Know-How to Pharmavant and its designees and to assist Pharmavant and its designees in its Manufacture of the Licensed Compound. After the expiration of such [***] period, and for a period of up to [***] from the Effective Date, Pharmavant may request continued reasonable assistance from Eisai at [***] and Eisai shall use commercially reasonable efforts to provide such reasonable assistance upon Pharmavant's request.

4.4.3 [***]. The Parties shall cooperate in good faith in order to finalize, and, within [***] of the Effective Date, execute, an Assignment and Assumption Agreement by and among the Parties and [***] substantially in the form of the draft agreement prepared by the Parties on the Effective Date pursuant to which Eisai shall assign and transfer to Pharmavant or its designee the [***] dated as of [***] between Eisai and [***], as may be amended from time to time with Pharmavant's consent (not to be unreasonably conditioned, withheld or delayed) [***]. Eisai shall, or shall cause its Affiliates to, as applicable, obtain the consent of [***] to the assignment by Eisai to Pharmavant of the [***] in accordance with the preceding sentence. Pharmavant hereby acknowledges and agrees that, from and after the effective date of the Assignment and Assumption Agreement, Pharmavant (a) shall assume and perform all of the duties, obligations, terms, provisions and covenants under and (b) shall discharge Eisai from any of the duties, obligations, terms, provisions and covenants under, in each case ((a) and (b)), the [***] after such effective date of assignment.

4.4.4 Assistance. Eisai shall, or shall cause its Affiliates to, as applicable, introduce to Pharmavant any or all Eisai Manufacturers in order to reasonably assist Pharmavant or its Affiliate in entering into new agreements directly with such Eisai Manufacturers to Manufacture the Licensed Product in the Field for the Territory, to the extent requested by Pharmavant in writing.

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

ARTICLE 5
FINANCIAL TERMS

5.1 Upfront Payment. Pharmavant shall pay to Eisai a one-time non-refundable, non-creditable payment in the aggregate amount of Fifteen Million Dollars ($15,000,000), payable as follows:

(a) Eight Million Dollars ($8,000,000) shall be paid in immediately available funds by wire transfer, within [***] of the Effective Date, in accordance with wire instructions to be provided in writing by Eisai in a written invoice submitted by Eisai to Pharmavant on or before the Effective Date; and

(b) Seven Million Dollars ($7,000,000) shall be paid through the issuance of shares of common stock of Roivant Sciences valued at the Share Price pursuant to the term of a share purchase agreement entered into by Eisai and Roivant Sciences on the Effective Date substantially in the form of Exhibit B attached hereto (the "Share Purchase Agreement").

5.2 Milestones.

5.2.1 Development Milestones.

(a) Pharmavant shall notify Eisai in writing (the "Development Milestone Event Notice") within [***] following the achievement by Pharmavant, its Affiliates, or its Sublicensees under this Agreement of each milestone event described under the heading "Development Milestone Event" in the below table in this Section 5.2.1(a) (each, a "Development Milestone Event") by the first Licensed Product, and Pharmavant shall thereafter pay the applicable one-time amount set forth below corresponding to the applicable Development Milestone Event in accordance with Section 5.2.1 (each, a "Development Milestone Payment"):

Development Milestone Event	Development Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Each Development Milestone Payment will be due and payable only once following the achievement of the corresponding Development Milestone Event regardless of the number of times such Development Milestone Event is achieved and/or the number of Licensed Products that achieve such Development Milestone Event. If any of Development Milestone Event (2), (3) or (4) is achieved prior to the achievement of Development Milestone Event (1), then the Development Milestone Payment for Development Milestone Event (1) shall be paid concurrently with the Development Milestone Payment for the first to occur of Development Milestone Event (2), (3) or (4), as the case may be.

5.2.2 Regulatory Milestones. Subject to the terms of this Section 5.2.2, Pharmavant shall notify Eisai within [***] following the achievement by Pharmavant, its Affiliates, or its Sublicensees under this Agreement of each milestone event described under the heading "Regulatory Milestone Event" in the below table in this Section 5.2.2 (each, a "Regulatory Milestone Event") by the first Licensed Product and Pharmavant shall thereafter pay the applicable one -time amount set forth below corresponding to the applicable Regulatory Milestone Event in accordance with Section 5.2.4 (each, a "Regulatory Milestone Payment") in respect of Licensed Products:

Regulatory Milestone Event	Regulatory Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each Regulatory Milestone Payment will be due and payable only once following the achievement of the corresponding Regulatory Milestone Event regardless of the number of times such Regulatory Milestone Event is achieved and/or the number of Licensed Products that achieve such Regulatory Milestone Event.

5.2.3 Commercialization Milestones.

(a) Pharmavant shall notify Eisai within [***] following the achievement by Pharmavant, its Affiliates, or its Sublicensees under this Agreement of each milestone event described under the heading "Commercialization Milestone Event" in the below table in this Section 5.2.3(a) (each, a "Commercialization Milestone Event") by the Licensed Product and Pharmavant shall thereafter pay the applicable one-time amount set forth below corresponding to the applicable Commercialization Milestone Event in accordance with Section 5.2.3(b) (each, a "Commercialization Milestone Payment") in respect of Licensed Products:

Commercialization Milestone Event	Commercialization Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Each Commercialization Milestone Payment will be due and payable only once following the achievement of the corresponding Commercialization Milestone Event regardless of the number of times such Commercialization Milestone Event is achieved and/or the number of Licensed Products that achieve such Commercialization Milestone Event. Pharmavant shall pay each Commercialization Milestone Payment within [***] after Eisai's receipt of notice from Pharmavant that any applicable Commercialization Milestone Event was first achieved; provided, that, if any of the Commercialization Milestone Events set forth in (5) through (7) of the above table are achieved for a given Licensed Product in a same Eisai Fiscal Year (i) the corresponding Commercialization Milestone Payment shall be payable [***] as follows: (A) [***] of the amount of the corresponding Commercialization Milestone Payment shall be paid within [***] after the date of receipt by Eisai of such notice that any applicable Commercialization Milestone Event was achieved and (B) [***] of the corresponding Commercialization Milestone Payment shall be paid within [***] after notice from Pharmavant for the immediate next Eisai Fiscal Year that such Commercialization Milestone Event was again achieved for such immediate next Eisai Fiscal Year; [***].

5.2.4 Invoice and Payment of Milestone Payments. Following Eisai's receipt of notice from Pharmavant that Pharmavant has achieved any Milestone Event or Milestone Events, Eisai shall invoice Pharmavant for the applicable Milestone Payment or Milestone Payments, and Pharmavant shall pay such Milestone Payment within[***] after receipt of each such invoice.

5.3 Royalties.

5.3.1 Royalty Rates. Subject to this Section 5.3.1, Pharmavant shall pay Eisai royalties on Annual Net Sales of the Licensed Product during the applicable Royalty Term, equal to the following portions of Annual Net Sales of the Licensed Product multiplied by the applicable royalty rate set forth below for such portion of Annual Net Sales during the applicable Royalty Term for the Licensed Product, which royalties shall be paid in accordance with Section 5.3.5.

Annual Net Sales in the Territory for the Licensed Product in a given Eisai Fiscal Year	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The applicable royalty rate set forth in the tables above shall apply only to that portion of the Annual Net Sales of the Licensed Product during a given Eisai Fiscal Year that falls within the indicated range. [***]

5.3.2 Royalty Term. Pharmavant's royalty obligations to Eisai under Section 5.3.1 shall apply, on a country-by-country and Licensed Product-by-Licensed Product basis, during the applicable Royalty Term for the Licensed Product in such country. Following the expiration of the applicable Royalty Term for the Licensed Product in a given country: (a) no further royalties shall be payable with respect to sales of the Licensed Product in such country (and no sales of Licensed Products in such country shall be counted for purposes of determining Net Sales for any period commencing on or after the expiration of such Royalty Term); and (b) the license granted to Pharmavant under this Agreement with respect to the Licensed Product in such country shall become fully paid-up, perpetual, irrevocable, and royalty-free in accordance with Section 10.1.

5.3.3 Royalty Reductions.

(a) Valid Claims. Subject to Section 5.3.3(d), the royalty rates set forth in Section 5.3.1 shall be reduced on a Licensed Product-by-Licensed Product and country-by-country basis, to (i) [***] of the rates otherwise payable pursuant to Section 5.3.1 during any portion of the Royalty Term in which there is not at least one Valid Claim of an Eisai Product Patent, Eisai Patent or Joint Patent which Covers the [***] Licensed Compound or Licensed Product in such country of sale, and (ii) [***] of the rates otherwise payable pursuant to Section 5.3.1 during any portion of the Royalty Term in which there is not at least one Valid Claim of an Eisai Product Patent, Eisai Patent or Joint Patent which Covers the Licensed Compound or Licensed Product in such country of sale.

(b) Generic Products. Subject to Section 5.3.3(d), if during the portion of the applicable Royalty Term of a Licensed Product in a particular country or geographic region in the Territory, one or more products are being sold in such country or geographic region in the Territory that are Generic Products with respect to such Licensed Product and there is Loss of Market Exclusivity for such Licensed Product in such country or geographic region in the Territory, then the royalty rates set forth in Section 5.3.1 with respect to such Licensed Product in such region or country shall be reduced by [***] of the applicable royalty rates that would otherwise be owed on such Net Sales of such Licensed Product in such region or country, for so long as the Loss of Market Exclusivity continues during the Royalty Term for the applicable Licensed Product in such region or country. Pharmavant will promptly notify Eisai of the occurrence of Loss of Market Exclusivity, which notice will specify the applicable Generic Product and country or geographic region in the Territory and include reasonable supporting evidence of such Loss of Market Exclusivity.

(c) Royalty Offset for Third Party Payments. If Pharmavant (or any of its Affiliates or sublicensees) in-licenses any Patents from any Third Party that may be used in order to Manufacture or Commercialize any Licensed Compound or Licensed Product in the Territory, then Pharmavant will have the right to credit [***] of any[***] payments attributable to the Manufacture or Commercialization of such Licensed Product in the Territory actually paid by Pharmavant or its Affiliates or sublicensees under such license in [***] against any royalty payment payable to Eisai under this Agreement for such Licensed Product.

(d) Cumulative Effect of Royalty Reductions and Offsets. In no event will the aggregate amount of royalty payments due to Eisai for a Licensed Product in the Territory in any given [***] during the Royalty Term for such Licensed Product be reduced to less than [***] of the amount that otherwise would have been due and payable to Eisai in such [***] for such Licensed Product but for the reductions set forth in Sections 5.3.3(a), (b) and (c); provided, that, if but for the proviso in this Section 5.3.3(d), the reductions under Sections 5.3.3(a), (b) and (c) would have reduced a royalty payment made by Pharmavant in any [***] by more than [***], then the amount of such reduction that exceeds[***] shall be carried over to royalty payments due and payable in subsequent [***].

5.3.4 [***].

5.3.5 Payment of Royalties; Royalty Reports. Pharmavant shall, within [***] following the end of each [***] in which a royalty payment pursuant to Section 5.3.1 accrues, (a) provide to Eisai a report specifying, for such [***]: (i) the amount of aggregate Net Sales of the Licensed Product in each country in the Territory; (ii) the applicable royalty rate under this Agreement; (iii) the royalty calculation and royalties payable in Dollars; and (iv) the amount of

withholding taxes, if any, required by Applicable Law to be deducted with respect to such royalties; and (b) make the royalty payments owed to Eisai under this Agreement in accordance with such royalty report within [***] following Pharmavant's receipt of a written invoice for the royalty payments specified in such royalty report. Pharmavant shall have the responsibility to account for and report sales of any Licensed Product in the Territory by its Sublicensee on the same basis as if such sales were Net Sales by Pharmavant. Pharmavant shall pay to Eisai any such royalty payments when due under this Agreement.

5.4 Additional Payment Terms.

5.4.1 Currency. All payments under this Agreement shall be made in US Dollars. Any sales incurred in a currency other than US Dollars shall be converted to the US Dollar equivalent using Pharmavant's then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into US Dollars.

5.4.2 Taxes. Each Party will pay any and all taxes levied on account of all payments it receives under this Agreement. If Applicable Law requires that taxes be withheld with respect to any payments by either Party to the other Party under this Agreement, such Party will provide advance (not less than [***]) written notice of such Party's intent to withhold any taxes. The Party required to withhold such taxes shall: [***]. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing or mitigating such taxes to the extent possible in compliance with Applicable Law. In addition, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

5.4.3 Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [***] above the prime rate as published in [***] or any successor thereto, at [***] or (b) the maximum rate permitted by Applicable Law, in each case calculated on the number of days such payment is delinquent, compounded [***].

5.5 Records; Audit Rights.

5.5.1 Records. Pharmavant shall keep, and shall cause its Affiliates to keep, complete, true and accurate books of accounts and records sufficient to determine and establish the royalties payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement. Such books and records shall be kept reasonably accessible and shall be made available for inspection for a [***] period in accordance with Section 5.5.2 below.

5.5.2 Inspection of Pharmavant Records. Upon reasonable prior written notice, Pharmavant shall permit an independent nationally recognized certified public accounting firm, appointed by Eisai and reasonably acceptable to Pharmavant to inspect the audited financial records of Pharmavant maintained pursuant to Section 5.5.1 above with respect to any Eisai Fiscal Year ending not more than [***] prior to Eisai's request to verify the amount of royalties due Eisai hereunder; provided, that, such inspection shall not occur more often than [***] unless a material error is discovered as part of such inspection, in which case Eisai shall have the right to conduct one more additional thorough inspection for such period. Any inspection conducted under this Section 5.5.2 shall be at the expense of Eisai, unless such inspection reveals any underpayment of the royalties due hereunder for the audited period by at least [***], [***]. Any underpayment of the royalties due hereunder shall be paid by Pharmavant to Eisai within [***] with interest on the underpayment at the rate specified in Section 5.4.4 from the date such payment was originally due, and any overpayment of the royalties due hereunder shall be credited against future amounts due by Pharmavant to Eisai.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1 Ownership.

6.1.1 Inventions.

(a) Eisai IP. Eisai or its Affiliates shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Eisai IP, Eisai Product Know-How and Eisai Product Patents.

(b) Pharmavant IP. Pharmavant shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Pharmavant IP, including all Pharmavant Background Patents, Pharmavant Background Know-How, Pharmavant Inventions and Pharmavant Invention Patents.

(c) Joint IP. All Joint IP will be owned jointly by the Parties. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to use Joint IP, practice the Joint IP, and grant licenses under its interest in Joint IP, as it deems appropriate and neither Party shall have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit such Joint IP, by reason of the joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting.

6.1.2 Clinical Data. All Clinical Data shall be [***].

6.1.3 Assignment Obligations.

(a) Each Party shall cause all employees of such Party (or any of its Affiliates) who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Inventions, whether or not patentable, resulting therefrom to such Party. With respect to any activip1b ties of a Party under this Agreement that are subcontracted to a Person that is not an employee, the Party retaining such subcontractor will include in the applicable subcontract an assignment to such Party of all rights in Inventions made by such subcontractor resulting from such activities, and in any event will include in the applicable subcontract a license to such Party that is sublicensable to the other Party under this Agreement, of any Inventions made by such contractor resulting from such activities.

(b) Pharmavant agrees to assign and hereby assigns all of its right, title and interest in and to all [***] to Eisai or its designee. Pharmavant agrees to sign all necessary documents and assignments or take such other actions as Eisai may reasonably request in order to perfect and enforce any and all of its rights in and to such [***]. [***] of perfecting and enforcing its rights in such [***] shall be borne by [***].

6.2 Prosecution and Maintenance.

6.2.1 Eisai First Right. Eisai will have the first right, but not the obligation, using patent counsel of its choice, to Prosecute and Maintain any Eisai Product Patents. Eisai shall give Pharmavant a reasonable opportunity to review and comment on the text of any application before filing Eisai Product Patents, shall reasonably consult with Pharmavant with respect thereto, shall supply Pharmavant with a copy of the application as filed, together with notice of its filing date and serial number, and shall reasonably provide advance copies of any substantive papers related to the filing, prosecution and maintenance of such Eisai Product Patents with sufficient time to provide Pharmavant with a reasonable opportunity to review and comment. Eisai shall keep Pharmavant advised of the status of the Eisai Product Patents and applications related thereto and shall promptly give notice to Pharmavant of the pending grant, lapse, revocation, surrender, invalidation or abandonment of any Eisai Product Patents. [***].

6.2.2 Pharmavant Fallback Right. Eisai shall give reasonable notice to Pharmavant if Eisai intends to cease Prosecution and Maintenance of any Eisai Product Patents in any country in the Territory and, in such case, Pharmavant shall have the right (but not the obligation) to continue the Prosecution and Maintenance of such Eisai Product Patents. If Pharmavant elects to continue such Prosecution and Maintenance, then Eisai shall execute such documents and perform such acts as may be reasonably necessary to effect a transfer of such responsibility in relation to the applicable Eisai Product Patents to Pharmavant in a timely manner to allow Pharmavant to continue such prosecution or maintenance. Pharmavant shall keep Eisai reasonably advised of the status of such Eisai Product Patents and, upon Eisai's request, shall reasonably provide advance copies of substantive papers related to the filing, prosecution and maintenance of such Eisai Product Patents. Pharmavant shall promptly give notice to Eisai of the grant, lapse, revocation, surrender, invalidation or abandonment of any such Eisai Product Patents. [***].

6.2.3 Pharmavant First Right. Pharmavant will have the first right, but not the obligation, using patent counsel of its choice, to Prosecute and Maintain, [***] any Pharmavant Patents. Pharmavant shall give Eisai a reasonable opportunity to review and comment on the text of any application before filing Pharmavant Patents, shall reasonably consult with Eisai with respect thereto, shall supply Eisai with a copy of the application as filed, together with notice of its filing date and serial number, and shall reasonably provide advance copies of any substantive papers related to the Prosecution and Maintenance of such Pharmavant Patents with sufficient time to provide Eisai with a reasonable opportunity to review and comment. Pharmavant shall keep Eisai advised of the status of the Pharmavant Patents and applications related thereto and shall promptly give notice to Eisai of the pending grant, lapse, revocation, surrender, invalidation or abandonment of any Pharmavant Patents. [***].

6.2.4 Eisai Fallback Right. Pharmavant shall give reasonable notice to Eisai if Pharmavant intends to cease Prosecution and Maintenance of any Pharmavant Invention Patents in any country in the Territory and, in such case, Eisai shall have the right (but not the obligation) to continue the Prosecution and Maintenance of such Pharmavant Invention Patents. If Eisai elects to continue such Prosecution and Maintenance, then Pharmavant shall execute such documents and perform such acts as may be reasonably necessary to effect a transfer of such responsibility in relation to the applicable Pharmavant Invention Patents to Eisai in a timely manner to allow Eisai to continue such Prosecution and Maintenance. Eisai shall keep Pharmavant reasonably advised of the status of such Pharmavant Invention Patents and, upon Pharmavant's request, shall reasonably provide advance copies of substantive papers related to the Prosecution and Maintenance of such Pharmavant Invention Patents. Eisai shall promptly give notice to Pharmavant of the grant, lapse, revocation, surrender, invalidation or abandonment of any such Pharmavant Invention Patents. [***].

6.2.5 Eisai Patents. Eisai will have the sole right, but not the obligation, using patent counsel of its choice, to Prosecute and Maintain, [***] any Eisai Patents. [***].

6.2.6 Joint Patents. The Parties shall mutually agree in good faith which Party shall be responsible for Prosecuting and Maintaining each Joint Patent on behalf of both Parties; provided, that, such activities shall, to the extent mutually agreed by the Parties, be handled by outside counsel free of ethical conflict and mutually agreeable to both Parties. [***].

6.2.7 Patent Prosecution Conferences. Each Party shall cause its patent counsel to confer no less frequently than every [***] regarding the status of all Patents for which it is responsible under this Section 6.2, and whether and in which countries foreign counterparts of such Patents shall be filed and any subject matter claimed in each. The Parties shall set the location, date, time and type of meeting (either in person, by teleconference, or by videoconference) so as to be mutually agreeable to the patent counsel of each Party.

6.3 Infringement by Third Parties.

6.3.1 Notice and Consultation. Each Party shall inform the other Party within [***] of becoming aware of (a) any infringement of or invalidity challenge to any Eisai Product Patents, Eisai Patents, Pharmavant Invention Patents or Joint Patents, including any declaratory judgment, opposition, post grant review, inter partes review, a Paragraph IV Certification in any Abbreviated New Drug Application or New Drug Application (each, as defined in the Federal Food, Drug, and Cosmetic Act) filing or similar action alleging the invalidity, unenforceability, unpatentability, or non-infringement with respect to such Eisai Product Patents, Eisai Patents, Pharmavant Invention Patents or Joint Patents, or any other actual or potential infringement of such Patents by a Third Party anywhere in the Territory, or (b) any misappropriation or misuse of Eisai Product Know-How, Eisai Background Know-How, Eisai Inventions, Pharmavant Inventions or Joint Inventions, in each case, to the extent such alleged infringing or misappropriating activities involve, as to the Licensed Product, any competing product with respect thereto (collectively, an "Infringement"). Pharmavant and Eisai shall thereafter consult and cooperate fully to determine and agree on a course of action, including the commencement of legal action by either or both Pharmavant and Eisai, to terminate or defend any Infringement (provided that, with respect to the defense of an invalidity challenge, such defense includes or involves at least one claim that relates to the Licensed Compound or any Licensed Product; provided, that, if the Parties are unable to agree upon whether to commence any action to defend any Infringement, Section 6.3.2 and Section 6.3.3 shall apply.

6.3.2 Eisai Right to Control. Unless otherwise agreed by the Parties, Eisai shall have the right to control (including to retain counsel to prosecute) any action to terminate or defend an Infringement for which notice to Pharmavant is provided of any (a) Eisai Product Patents, (b) Eisai Product Know-How and (c) Eisai IP. Eisai shall consult with Pharmavant, and Pharmavant shall have the right to review and comment on any material submissions to be made by Eisai in connection with any such action. In any such action, Pharmavant shall have the right to be represented by counsel of its own choice, [***].

6.3.3 Pharmavant Right to Control. Unless otherwise agreed by the Parties, Pharmavant shall have the right to control (including to retain counsel to prosecute) any action to terminate or defend an Infringement for which notice is provided under Section 6.3.1 of any (a) Pharmavant Invention Patents and (b) Pharmavant Inventions. Pharmavant shall consult with Eisai and Eisai shall have the right to review and comment on, any material submissions to be made by Pharmavant in connection with any such action. In any such action, Eisai shall have the right to be represented by counsel of its own choice, [***].

6.3.4 Joint IP. The Parties shall mutually agree in good faith which Party shall be responsible for controlling (including to retain counsel to prosecute) any action to terminate or defend an Infringement of any Joint IP. In any such action, the controlling Party shall consult with the non-controlling Party and the non-controlling Party shall have the right to review and comment on any material submissions to be made by the controlling Party connection with any such action. In any such action, the other Party shall have the right to be represented by counsel of its own choice, [***].

6.3.5 Fallback Right. The controlling Party shall give reasonable notice to the non-controlling Party if such controlling Party elects not to initiate, or intends to cease an action to terminate or defend an Infringement for which notice is provided under Section 6.3.1. In each such case, for (a) Eisai Product Patents, (b) Eisai Product Know-How, (c) Pharmavant Invention Patents and (d) Pharmavant Inventions, to the extent consistent with the controlling Party's global intellectual property strategy, the non-controlling Party shall have the right (but not the obligation) to initiate or continue such action. If the non-controlling Party elects to initiate or continue such action, then the controlling Party shall execute such documents and perform such acts as may be reasonably necessary to effect a transfer of such responsibility in relation to the applicable Patents to the non-controlling Party in a timely manner to allow the non-controlling Party to initiate or continue such action. The non-controlling Party shall keep the controlling Party reasonably advised of the status of such action and, upon the controlling Party request, shall reasonably provide advance copies of substantive papers related to the action.

6.3.6 Settlements. For any action involving (a) Eisai Product Patents, (b) Eisai Product Know-How, (c) Pharmavant Invention Patents and (d) Pharmavant Inventions, the controlling Party shall not enter into any settlement, consent judgment or other disposition of any action to terminate or defend an Infringement without the prior written consent of the non-controlling Party, which consent shall not be unreasonably conditioned, withheld or delayed; provided, that, any such settlement, consent judgment or other disposition of any action or proceeding by a Party under this Section 6.3 will not, without the consent of the other Party, (a) impose any liability or obligation on such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect.

6.3.7 Cooperation. In connection with any action to terminate or defend an Infringement, Pharmavant and Eisai will reasonably cooperate and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other Party informed of developments in any such action or proceeding, including, to the extent permissible by Applicable Law, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

6.3.8 Joinder. For any action to terminate or defend any Infringement, in the event that a controlling Party is unable to initiate or prosecute such action solely in its own name, and it is necessary that the non-controlling Party join such action to do so, the non-controlling Party will join such action and shall execute and cause its Affiliates to execute all documents necessary for the controlling such Party to initiate litigation to prosecute and maintain such action.

6.3.9 Costs/Recoveries. A Party bringing a claim, suit or action to terminate or defend any Infringement will be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages from such Third Party in such suit or action, such recovery will [***]. If such recovery is insufficient to cover all such costs and expenses of both Parties, it will be [***]. If, after such reimbursement, any funds remain from such damages, all such remaining funds will be allocated between the Parties as follows: (a) if Eisai controls enforcement in accordance with this Section 6.3, Eisai shall be entitled to receive [***] of all remaining proceeds and (b) if Pharmavant controls enforcement in accordance with this Section 6.3, Eisai shall be entitled to [***]

6.3.10 Cooperation and Patent Term Restoration. The Parties agree to reasonably cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. § 102(c) for U.S. patents and patent applications with respect to the Licensed Compound and any Licensed Products. The Parties shall cooperate with each other, including by providing necessary information and assistance as the other Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents (collectively "Patent Term Restoration") in any country in the Territory where applicable to any Eisai Product Patents, Eisai Patents, Pharmavant Background Patents, Pharmavant Invention Patents or Joint Patents. Eisai, following consultation with Pharmavant shall have the right to select which Patent or Patents to file for Patent Term Restoration and to control (including to retain counsel to prosecute) any such Patent Term Restoration filing.

6.3.11 Patent Listings. The Parties shall reasonably agree upon the filings to be made with Regulatory Authorities in the Territory with respect to Eisai Product Patents, Eisai Patents, Pharmavant Background Patents, Pharmavant Invention Patents or Joint Patents that contain any claims that cover a Licensed Product including without limitation as required or allowed (a) in the United States, in the FDA's Orange Book, (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 and (c) in any other country in the Territory under the equivalent Regulatory Authorities in such country. If the Parties are unable to agree, Eisai will retain final decision-making authority with respect to any such listing; provided, that, in making such decision, Eisai shall reasonably consider in good faith Pharmavant's position in connection therewith.

6.3.12 Disclosure of Inventions. Each Party will promptly disclose to the other Party all invention disclosures submitted to such Party by its or its Affiliates' employees describing Inventions. Each Party will also respond promptly to reasonable requests from the other Party for more information relating to such Inventions. Inventorship of such Inventions and whether the Patents claiming such Inventions are deemed to be the Eisai Product Patents shall be determined in good faith by the Parties prior to the filing of patent application claiming such Inventions.

6.3.13 Personnel Obligations. Prior to receiving any Confidential Information or beginning work under this Agreement relating to the Development or Commercialization of the Licensed Compound or any Licensed Products, each employee, agent or independent contractor of Pharmavant or Eisai or of either Party's respective Affiliates will be bound in writing by non-disclosure and invention assignment obligations which are consistent with the obligations of Pharmavant or Eisai under this Agreement; provided, that, to the extent necessary in the case of a Third Party (a) such Third Party shall agree to grant Pharmavant or Eisai, as the case may be, an exclusive license with the right to grant sublicenses with respect to resulting Inventions and Patents and (b) the period of time with respect to non-disclosure obligations may be shorter, but in no event less than [***] from the effective date of the written obligation.

6.4 Common Interest Agreement. At the request of either Party, the Parties will negotiate in good faith to enter into a common interest agreement with respect to the subject matter of this Article 6. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

6.5 Defense.

6.5.1 Notice. Each Party shall promptly notify the other Party of any claim alleging that the Development, Manufacture or Commercialization of any Licensed Product in the Territory infringes, misappropriates, or otherwise violates any Patents, Know-How, or other intellectual property rights of any Third Party ("Third Party Infringement"). In any such instance, the Parties shall as soon as practicable thereafter discuss in good faith the best response to such notice of Third Party Infringement.

6.5.2 Pharmavant Right to Defend. Pharmavant shall have the first right, but not the obligation, to defend, and take other actions (including to settle) with respect to, any such claim of Third Party Infringement, at Pharmavant's sole discretion, cost, and expense; provided, that, (a) Pharmavant will discuss in good faith and coordinate with Eisai in connection therewith and Pharmavant will consider in good faith and reasonably address Eisai's input and comments with respect thereto and (b) Pharmavant will not, without the prior written consent of Eisai, enter into any settlement, consent judgment or other disposition of any action or proceeding that would (i) impose any liability or obligation on Eisai, or (ii) admit the invalidity of, or otherwise impair, any Eisai Product Patents or Eisai Patents without the prior written consent of Eisai. Eisai shall have the right to be represented in any such action by counsel of its own choice at [***]. Any damages or other monetary awards that are awarded to a Third Party in any Third Party Infringement or in connection with a settlement of any such Third Party Infringement that is defended by Pharmavant under this Section 6.5.2 will be borne [***].

6.5.3 Eisai Fallback Right. If Pharmavant determines not to institute an action or proceeding with respect to a given Third Party Infringement pursuant to Section 6.5.2 or if Pharmavant or its designee fails to defend such Third Party Infringement in the Territory or to file an action to defend such Third Party Infringement in the Territory within [***] after a written request from Eisai to do so, or if Pharmavant discontinues the defense of any such action after filing without abating such Third Party Infringement, then Eisai shall have the right, but not the obligation, to defend, and take other actions (including to settle) with respect to, any such claim of Third Party Infringement, at Eisai's sole discretion, [***] and shall keep Pharmavant reasonably informed with respect to any such enforcement action; provided, that, Eisai shall not, without the prior written consent of Pharmavant, enter into any settlement, consent judgment or other disposition of any action or proceeding that would (i) impose any liability or obligation on Pharmavant, (ii) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to Pharmavant under this Agreement, or (iii) otherwise adversely affect the licenses or other rights granted to Pharmavant hereunder in any respect. Any damages or other monetary awards that are awarded to a Third Party in any Third Party Infringement or in connection with a settlement of any such Third Party Infringement that is defended by Eisai under this Section 6.5.3 will be shared as follows: (A) Pharmavant shall bear [***] of such damages or monetary awards and (B) Eisai shall bear [***] of such damages or monetary awards.

6.6 Pharmavant Trademarks. Pharmavant and its Affiliates shall have the exclusive right, but not the obligation, to brand the Licensed Products using trademarks and trade names it determines appropriate for the Licensed Products, which may vary for different countries (the "Pharmavant Trademarks"). Pharmavant shall exclusively own all rights in and goodwill associated with the Pharmavant Trademarks and shall register, maintain and defend the Pharmavant Trademarks [***]. The benefit of the Pharmavant Trademarks shall inure entirely to Pharmavant.

ARTICLE 7
CONFIDENTIALITY

7.1 Nondisclosure. Each Party hereby agrees that a Party (the "Receiving Party") which receives any Confidential Information of the other Party (the "Disclosing Party") pursuant to this Agreement shall: (a) maintain in confidence such Confidential Information using not less than the efforts that such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of efforts; (b) not disclose such Confidential Information to any Third Party without first obtaining the prior written consent of the Disclosing Party (which shall not be unreasonably conditioned, delayed or withheld), except for disclosures expressly permitted pursuant to this Article 7; and (c) not use such Confidential Information for any purpose except those permitted under this Agreement, including, in the case of each Party, the exercise of the rights and licenses granted to such Party hereunder. The obligations of confidentiality, non-disclosure, and non-use under this Section 7.1 shall be in full force and effect from the Effective Date until the [***] of the date of termination

or expiration of this Agreement. The Receiving Party shall return all copies of or destroy the Confidential Information of the Disclosing Party disclosed or transferred to it by the other Party pursuant to this Agreement, within [***] after the expiration or termination of this Agreement; provided, that, the Receiving Party may retain (i) Confidential Information of the Disclosing Party to exercise rights and licenses which expressly survive such termination or expiration pursuant to this Agreement; and (ii) one copy of all other Confidential Information in its archives solely for the purpose of establishing the contents thereof.

7.2 Exceptions.

7.2.1 General. Section 7.1 shall not apply with respect to any portion of the Confidential Information of the Disclosing Party to the extent that such Confidential Information:

(a) was known to the Receiving Party or any of its Affiliates, as evidenced by written records, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(b) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(c) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party, without any breach by the Receiving Party of its obligations hereunder; or

(d) is independently developed by or for the Receiving Party or any of its Affiliates, as evidenced by contemporaneous written records, without reference to or reliance upon the Disclosing Party's Confidential Information.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

7.3 Authorized Disclosure.

7.3.1 Disclosure. Notwithstanding Section 7.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party in the following instances:

(a) subject to Section 7.5, to comply with Applicable Law (including the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange in any jurisdiction in the Territory) (collectively, the "Securities Regulators") or with judicial process (including prosecution or defense of litigation), if, in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance or for such judicial process (including prosecution or defense of litigation);

(b) disclosure to governmental or other regulatory agencies in order to obtain or maintain approval to conduct Clinical Trials, or to Commercialize the Licensed Products under this Agreement, in each case, in accordance with this Agreement; provided, that, reasonable steps are taken to ensure confidential treatment of such Confidential Information to the extent available;

(c) disclosure to any of its or its Affiliates' officers, employees, directors, consultants, agents, or Affiliates, including: (i) in the case of Pharmavant, any actual or potential collaborators, licensees, or Sublicensees; (ii) in the case of either Party, to such Party's permitted subcontractors for purpose of such subcontractors performing obligations of such Party under this Agreement as it deems necessary or advisable in the course of conducting activities in accordance with this Agreement in order to carry out its responsibilities or exercise its rights under this Agreement (including the exercise of the rights and licenses granted to the relevant Party under this Agreement); and (iii) in the case of either Party, to such Party's actual or potential acquirers, investment bankers or other financial advisors, or actual or potential investors, lenders or other financial partners; provided, that, prior to any such disclosure, each such disclosee is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 7 to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); provided, that, in each of the above situations in this Section 7.3.1(c), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 7.3.1(c) to treat such Confidential Information as required under this Article 7;

(d) disclosure to its advisors (including attorneys and accountants) in connection with activities under this Agreement; provided, that, prior to any such disclosure, each such disclose is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 7 (provided, that, in the case of legal advisors and accountants, no written agreement shall be required), to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement; provided, that, in each of the above situations in this Section 7.3.1(d), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 7.3.1(d) to treat such Confidential Information as required under this Article 7; and

(e) disclosure of any pharmacovigilance information originating from a Party its Affiliates, or the other Party to Regulatory Authorities, investigators, ethical committees and internal review boards, and any other Third Parties that have a need to know such information according to each Party's risk management and adverse event reporting policies and requirements.

7.3.2 Terms of Disclosure. If and whenever any Confidential Information is disclosed in accordance with Section 7.3.1, such disclosure shall not cause any such information to cease to be Confidential Information, except to the extent that such disclosure results in a public disclosure of such information other than by breach of this Agreement. Subject to Section 7.6, the Receiving Party will notify the Disclosing Party of the Receiving Party's intent to make any disclosures pursuant to Section 7.3.1 sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, and the Receiving Party will provide reasonable assistance to the Disclosing Party with respect thereto; provided that, in such event, the Receiving Party will use reasonable measures to ensure confidential treatment of such information and will only disclose such Confidential Information of the Disclosing Party as is necessary for the purposes of Section 7.3.1.

7.4 Terms of this Agreement. The Parties agree that this Agreement shall be deemed to be Confidential Information of both Eisai and Pharmavant, and each Party agrees not to disclose this Agreement or any terms hereof without obtaining the prior written consent of the other Party; provided, that each Party may disclose this Agreement or any terms hereof in accordance with the provisions of Sections 7.3 or 7.5, as applicable.

7.5 Securities Filings; Disclosure under Applicable Law. Each Party acknowledges and agrees that the other Party may submit this Agreement to, or file this Agreement with, the Securities Regulators or to other Persons as may be required by Applicable Law, and if a Party submits this Agreement to, or files this Agreement with, any Securities Regulator or other Person as may be required by Applicable Law, such Party agrees to consult with the other Party with respect to the preparation and submission of a redacted version of this Agreement in compliance with Applicable Law. Notwithstanding the foregoing, if a Party determines that disclosure of the terms of this Agreement or material activities hereunder is required in a filing or other submission to a Securities Regulator or other Person, and such Party has: (a) provided copies of the disclosure to the other Party reasonably in advance under the circumstances of such filing or other disclosure; (b) promptly notified the other Party in writing of such requirement and any respective timing constraints; and (c) given the other Party reasonable time under the circumstances from the date of provision of a copy of such disclosure to comment upon and request confidential treatment for such disclosure, then such Party shall have the right to make such disclosure at the time and in the manner reasonably determined by its counsel to be required by the Securities Regulator or the other Person.

If a Party seeks to make a disclosure as required by a Securities Regulator or other Person as may be required by Applicable Law as set forth in this Section 7.5 and the other Party provides comments in accordance with this Section 7.5, the Party seeking to make such disclosure or its counsel, as the case may be, shall use good-faith efforts to consider the incorporation of such comments. The contents of any filing or submission that has been disclosed in accordance with this Section 7.5 may be re-filed or re-submitted by such reviewing Party or disclosing Party without a requirement to repeat the process contemplated in clauses (a) through (c) above.

7.6 Press Releases. Subject to this Section 7.6 and Section 7.7, each Party agrees not to, and agrees to cause its Affiliates not to, issue any press release disclosing the material activities hereunder, or the transactions contemplated hereby, unless such press release is approved by the other Party in writing, provided such approval shall not be unreasonably conditioned, delayed or withheld. For any press releases made by a Party, the Party issuing the press release shall provide the other Party with a copy of the press release for review and comment at least [***] before the proposed release. Notwithstanding the foregoing, each Party will be authorized to make any disclosure, without the approval of the other Party, that is required by Applicable Law (including the U.S. Securities Act of 1933, as amended, and the U.S. Securities Exchange Act of 1934, as amended) or the rules of any Securities Regulator, or by judicial process, subject to and in accordance with Section 7.5. The contents of any press release that has been reviewed and approved by a reviewing Party may be re-released by such reviewing Party or publishing Party without a requirement for re-approval.

7.7 Publication of Results. During the Term, Pharmavant will have the sole and exclusive right to publish on the Development, Manufacture, performance of Medical Affairs Activities and Commercialization of the Licensed Compound and the Licensed Products in the Field in the Territory; provided, that, Pharmavant will provide a copy of any proposed abstract, publication or presentation to Eisai at least [***] prior to Pharmavant's intended submission for publication or presentation so that Eisai may review such proposed abstract, publication or presentation and (a) provide comments to Pharmavant on such proposed abstract, publication or presentation, which comments Pharmavant will consider in good faith and (b) if applicable, identify and require Pharmavant to delete from such abstract, publication or presentation any of Eisai's Confidential Information, which Confidential Information Pharmavant will delete from such proposed abstract, publication or presentation prior to disclosure thereof; but, further provided however that, for purposes of Eisai's rights under the foregoing clause (b), [***] shall not be deemed Confidential Information of Eisai. Eisai will use reasonable efforts to complete such review at least [***] prior to Pharmavant's intended publication or presentation date. Further, Eisai will have the right to request a reasonable delay in the publication or presentation date in order to protect patentable information, in which case Pharmavant will delay submission for a period of [***] (or such other period as may be agreed by the Parties in writing) to enable Eisai to file patent applications protecting Eisai's rights in such information. Pharmavant subsequently will provide Eisai a copy of the abstract, publication or presentation at the time of its submission. Without limiting the foregoing, Pharmavant agrees to acknowledge the contributions of Eisai and its employees in all abstracts, publications or presentations, as scientifically appropriate. After the release of any abstract, publication or presentation by Pharmavant in accordance with this Section 7.7, Pharmavant may further disclose the information contained in such abstract, publication or presentation without the need for further notice to, or review by, Eisai under this Section 7.7 or otherwise, so long as such information remains true, correct, and the most current information with respect to the subject matters set forth therein.otherwise, so long as such information remains true, correct, and the most current information with respect to the subject matters set forth therein.

7.8 Disclosure of Clinical Data. Pharmavant agrees with respect to any such disclosure to comply with the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results.

7.9 Use of Names. Except as otherwise expressly set forth herein, neither Party (or any of its respective Affiliates) shall use the name, trademark, trade name, or logo of the other Party or any of its Affiliates, or its or their respective employees, in any publicity, promotion, news release, or other public disclosure relating to this Agreement or its subject matter, without first obtaining the prior written consent of the other Party; provided, that, such consent shall not be required to the extent (a) use thereof may be required by Applicable Law, including the rules of any securities exchange or market on which a Party's or its Affiliate's securities are listed or traded, or (b) use is limited to the other Party's name and logo in non-confidential presentations, company website, or collateral materials, in each case to identify such other Party as a licensing partner.

7.10 [***].

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) such Party is duly organized, validly existing, and in good standing under the Applicable Law of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with its terms, except to the extent that enforcement of the rights and remedies created hereby is subject to: (i) bankruptcy, insolvency, reorganization, moratorium, and other similar laws of general application affecting the rights and remedies of creditors; or (ii) laws governing specific performance, injunctive relief, and other equitable remedies;

(d) the execution, delivery, and performance of this Agreement by such Party does not breach or conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which such Party (or any of its Affiliates) is a partyor by which such Party (or any of its Affiliates) is bound, nor violate any Applicable Law of any Governmental Authority having jurisdiction over such Party (or any of its Affiliates);

(e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency, or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or shall be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except (i) as may be required to conduct Clinical Trials or to seek or obtain Regulatory Approvals or prepare and submit Regulatory Materials; or (ii) as set forth in Article 7;

(f) it has obtained all necessary authorizations, consents, and approvals of any Third Party that is required to be obtained by it for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except as may be required to conduct Clinical Trials or to seek or obtain Regulatory Approvals or prepare and submit Regulatory Materials;

(g) there are no legal claims, judgments, or settlements against or owed by either Party or any of its Affiliates, or pending or, to either Party's knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations; and

(h) to its knowledge, neither such Party nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of either Party or any of its Affiliates: (i) has taken any action in violation of any applicable Anti-Corruption Laws; or (ii) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of: (A) influencing any act or decision of any Public Official in his or her official capacity; (B) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty; (B) securing any improper advantage; (D) or inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business.

8.2 Representations and Warranties of Eisai. Eisai hereby represents and warrants to Pharmavant, as of the Effective Date, as follows:

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]

(h) [***]

(i) [***]

(j) [***]

(k) [***]

(l) [***]

(m) [***]

(n) [***]

(o) [***]

8.3 Representations and Warranties of Pharmavant. [***]

8.4 Covenants.

8.4.1 Mutual Covenants. Each Party hereby covenants to the other Party as follows:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]

(f) [***].

8.4.2 Additional Covenants of Eisai.

(a) [***].

(b) [***].

8.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NON-INFRINGEMENT OF ANY THIRD PARTY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT. WITHOUT LIMITING THE FOREGOING, THE PARTIES AGREE THAT THE MILESTONE EVENTS, ROYALTY TIERS AND NET SALES LEVELS SET FORTH IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS, AND ROYALTY OBLIGATIONS IF SUCH MILESTONE EVENTS OR NET SALES LEVELS ARE ACHIEVED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP, MANUFACTURE, OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

ARTICLE 9
INDEMNIFICATION; INSURANCE

9.1 Indemnification by Pharmavant. Pharmavant shall indemnify, defend, and hold harmless Eisai, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "Eisai Indemnitees") from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) [***];

(b) the gross negligence or willful misconduct of Pharmavant or its Affiliates or Sublicensees or its or their respective directors, officers, employees, or agents, including its Third Party subcontractors, in connection with Pharmavant's performance of its obligations under this Agreement; or

(c) any material breach by Pharmavant of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;provided, that, in each case ((a)-(c)), such indemnity shall not apply to the extent Eisai has an indemnification obligation pursuant to Sections 9.2(a), 9.2(b), 9.2(c) or 9.2(d) for such Damages.

9.2 Indemnification by Eisai. Eisai shall indemnify and hold harmless Pharmavant, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "Pharmavant Indemnitees"), from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) [***];

(b) [***];

(c) the gross negligence or willful misconduct of Eisai or its Affiliates or its or their respective directors, officers, employees, or agents, in connection with Eisai's performance of its obligations under this Agreement; or

(d) any material breach by Eisai of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;

provided, that, in each case ((a)-(e)), such indemnity shall not apply to the extent Pharmavant has an indemnification obligation pursuant to Sections 9.1(a), 9.1(b), or 9.1(c) for such Damages.

9.3 Procedure.

9.3.1 Indemnification Claim Notice. If a Party is seeking indemnification under Section 9.1 or Section 9.2, as applicable (the "Indemnitee"), it shall inform the other Party (the "Indemnitor") of the claim giving rise to the obligation to indemnify pursuant to Section 9.1 or Section 9.2, as applicable, as soon as reasonably practicable after receiving notice of the Third Party Claim (an "Indemnification Claim Notice"); provided, that, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnitee's rights to indemnification under Section 9.1 or Section 9.2, as applicable, except to the extent that such delay or failure materially prejudices the Indemnitor's ability to defend against the relevant Third Party Claim.

9.3.2 Right to Assume Defense. The Indemnitor shall have the right, upon written notice given to the Indemnitee within [***] after receipt of the Indemnification Claim Notice, to assume the defense of any such Third Party Claim for which the Indemnitee is seeking indemnification pursuant to Section 9.1 or Section 9.2, as applicable. The Indemnitee shall cooperate with the Indemnitor and the Indemnitor's insurer as the Indemnitor may reasonably request, [***]. The Indemnitee shall have the right to participate, [***] and with counsel of its choice, in the defense of any Third Party Claim that has been assumed by the Indemnitor.

9.3.3 Right to Settle. The Indemnitor shall not settle any Third Party Claim without first obtaining the prior written consent of the Indemnitee, not to be unreasonably withheld, conditioned, or delayed; provided, that, the Indemnitor shall not be required to obtain such consent if the settlement: (a) involves only the payment of money and shall not result in the Indemnitee (or other Eisai Indemnitees or Pharmavant Indemnitees, as applicable) becoming subject to injunctive or other similar type of relief; (b) does not require an admission by the Indemnitee (or other Eisai Indemnitees or Pharmavant Indemnitees, as applicable); and (c) does not adversely affect the rights or licenses granted to the Indemnitee (or its Affiliate) under this Agreement. The Indemnitee shall not settle or compromise any such Third Party Claim without first obtaining the prior written consent of the Indemnitor.

9.3.4 Disputes. If the Parties cannot agree as to the application of Section 9.1 or Section 9.2, as applicable, to any Third Party Claim, pending the resolution of the dispute pursuant to Section 11.6.2, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 9.1 or Section 9.2, as applicable, upon resolution of the underlying Third Party Claim. In each case, the Indemnitee shall reasonably cooperate with the Indemnitor and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 7.

9.4 Insurance. Each Party shall maintain a program of insurance or self-insurance sufficient to fulfill its obligations under this Agreement which are [***] at all times during which the Licensed Compound or any Licensed Product is being clinically tested in human subjects or commercially distributed or sold. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 9. Each Party shall provide the other Party with written evidence of such insurance upon request, which evidence shall be treated as such Party's Confidential Information. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, nonrenewal or material change in such insurance.

9.5 LIMITATION OF LIABILITY. NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES), WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION, OR OTHERWISE, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THATPARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. [***].

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

ARTICLE 10
TERM AND TERMINATION

10.1 Term; Expiration.

10.1.1 Term. The term of this Agreement shall commence on the Effective Date and unless earlier terminated in accordance with this Article 10, this Agreement shall remain in effect until it expires as follows (the "Term"):

(a) on a country-by-country basis, this Agreement shall expire on the date of the expiration of the Royalty Term with respect to the Licensed Product in such country; and

(b) this Agreement shall expire in its entirety upon the expiration of all applicable Royalty Terms under this Agreement with respect to all Licensed Products in all countries in the Territory.

10.1.2 Effect of Expiration. Upon the expiration of the Term pursuant to Section 10.1.1, the following terms shall apply:

(a) Licenses after Licensed Product Expiration. Upon the expiration of the Term with respect to a Licensed Product in a given country pursuant to Section 10.1.1(a), the licenses set forth in Section 2.1 with respect to such Licensed Product in such country shall become fully paid-up, perpetual, irrevocable and royalty-free.

(b) Licenses after Expiration of Agreement. Upon the expiration of the Term with respect to this Agreement in its entirety pursuant to Section 10.1.1(b), the licenses set forth in Section 2.1 with respect to all Licensed Products in all countries in the Territory shall become fully paid-up, perpetual, irrevocable, and royalty-free.

10.2 Termination for Material Breach.

10.2.1 Termination Notice. This Agreement may be terminated in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis by a Party for the material breach by the other Party of this Agreement; provided, that, the breaching Party has not cured such breach within [***]after the date of written notice to the breaching Party of such breach (the "Cure Period"), which notice shall describe such material breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement. Notwithstanding the foregoing, if such material breach by its nature cannot be cured within the foregoing Cure Period or is incurable, but the consequences of such breach can be reasonably alleviated but not within the foregoing

Cure Period, then such Cure Period shall be extended if, prior to the end of the initial [***] Cure Period, the non-terminating Party provides a reasonable written plan for curing or reasonably alleviating the consequences of such material breach and thereafter uses Commercially Reasonable Efforts (or commercially reasonable efforts where Eisai is the breaching Party) to cure or alleviate such material breach in accordance with such written plan. Notwithstanding the foregoing, in no event shall such Cure Period extend for more than [***] after the breaching Party provides such written plan to the other Party, subject to Section 10.2.2.

10.2.2 Disagreement as to Material Breach. Notwithstanding Section 10.2.1, if the Parties in good faith disagree as to whether there has been a material breach of this Agreement, then: (a) the Party that disputes whether there has been a material breach may contest the allegation by referring such matter, within [***] following its receipt of notice of alleged material breach, for resolution in accordance with Section 11.6.2; (b) unless otherwise determined by the arbitrators pursuant to Section 11.6.2, the relevant Cure Period with respect to such alleged material breach shall be tolled from the date on which the Party that disputes whether there has been a material breach notifies the other Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement; and (c) during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

10.3 Termination for Challenge. Except to the extent the following is unenforceable under the Applicable Law of a particular jurisdiction where a Patent within any Eisai Product Patents or Eisai Patents, is pending or a patent within any such Patents issued, Eisai may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis upon written notice if Pharmavant or any of its Affiliates, Sublicensees or distributors initiates a Challenge or Assists a Third Party in initiating a Challenge.

10.4 Termination for Bankruptcy.

10.4.1 If either Party makes a general assignment for the benefit of, or an arrangement or composition generally with, its creditors, appoints or suffers appointment of an examiner or of a receiver or trustee over all or substantially all of its property, passes a resolution for its winding up, or files a petition under any bankruptcy or insolvency act or law or has any such petition filed against it which is not dismissed, discharged, bonded, or stayed within [***] after the filing thereof (each, an "Insolvency Event"), the other Party may terminate this Agreement in its entirety, effective immediately upon written notice to such Party.

10.4.2 If this Agreement is terminated due to the rejection of this Agreement by or on behalf of Eisai due to an Insolvency Event, all licenses and rights to licenses granted under or pursuant to this Agreement by Eisai to Pharmavant are and shall otherwise be deemed to be licenses of rights to "intellectual property." The Parties agree that Pharmavant, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections

under any applicable insolvency statute, and that upon commencement of an Insolvency Event by or against Eisai, Pharmavant shall be entitled to a complete duplicate of or complete access to (as Pharmavant deems reasonably appropriate) any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Pharmavant: (a) upon any such commencement of a bankruptcy proceeding (or other Insolvency Event) upon written request therefore by Pharmavant, unless Eisai elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered pursuant to (a) above, upon the rejection of this Agreement by or on behalf of Eisai, then upon written request therefore by Pharmavant. The provisions of this Section 10.4.2 shall be: (i) without prejudice to any rights Pharmavant may have arising under any applicable insolvency statute or other Applicable Law; and (ii) effective only to the extent permitted by Applicable Law.

10.5 [***].

10.6 Effects of Termination.

10.6.1 Termination by Eisai for Material Breach or Bankruptcy, or by Eisai for Challenge. [***]. Upon termination of this Agreement in its entirety or, subject to Section 10.6.1(f), with respect to a country or countries in the Territory or with respect to a Licensed Product: by Eisai, in accordance with Section 10.2, Section 10.3 or Section 10.4 [***]:

(a) all licenses granted by Eisai to Pharmavant under this Agreement shall terminate;

(b) all rights granted by Eisai to Pharmavant under this Agreement shall terminate;

(c) Pharmavant shall (i) grant, and hereby does grant, to Eisai or its designee, effective as of the effective date of such termination, [***] license under the Pharmavant Inventions, Pharmavant Invention Patents, Joint Inventions and Joint Patents, and (ii) grant, and hereby does grant, to Eisai, effective as of the effective date of such termination, [***] license under the Pharmavant Background Know-How and Pharmavant Background Patents, in each case, that are necessary or reasonably useful for the Development, Manufacture or Commercialization of the Terminated Products in the Field in the Terminated Territory as of the effective date of termination, in each case ((i) and (ii)), to Develop, Manufacture and Commercialize the Terminated Products in the Field in the Terminated Territory; provided, that, to the extent necessary in the case of any such Pharmavant Background Know-How and such Pharmavant Background Patents that are in-licensed by Pharmavant from a Third Party Eisai shall be responsible for (A) making any payments (including royalties, milestones and other amounts) payable by Pharmavant (or any of its Affiliates) to such Third Party under any agreement between Pharmavant (or its Affiliate) and the Third Party pursuant to which Pharmavant obtained a license to such Pharmavant Background Know-How or Pharmavant Background Patents, which payment

is triggered by the grant or exercise of such license to such Pharmavant Background Know-How or Pharmavant Background Patents by or on behalf of Eisai (or any of its Affiliates or Sublicensees) pursuant to this Section 10.6.1, and (B) complying with any other obligations included in any such Third Party agreements that are applicable to the grant to Eisai of such license or to the exercise of such license by Eisai or any of its Affiliates or sublicensees;

(d) the Parties will negotiate in good faith the terms and conditions of a written plan (the "Eisai Transition Plan") pursuant to which Pharmavant and Eisai will effectuate and coordinate an orderly transition of the relevant obligations and rights to Eisai as reasonably necessary for Eisai to Develop, Manufacture and Commercialize Terminated Products after termination of this Agreement (either in its entirety or with respect to the Terminated Territory, as applicable) in a manner consistent with Applicable Law and standards of ethical conduct of human Clinical Trials as and to the extent set forth in this Article 10. The Eisai Transition Plan shall provide that Pharmavant shall:

(i) where permitted by Applicable Law, transfer to Eisai all of its right, title and interest in all Regulatory Materials then Controlled by Pharmavant that are solely applicable to the Terminated Products in the Terminated Territory, or to the extent not so transferrable, Pharmavant shall take all reasonable actions to make available to Eisai or its designee the benefits of such Regulator Materials, including upon Eisai's request, by providing a right of reference to such Regulatory Materials Controlled by Pharmavant for the Terminated Products on the effective date of termination, to the extent necessary for Eisai to Develop and Commercialize Terminated Products;

(ii) at Eisai's request and expense, notify the applicable Regulatory Authorities in the Terminated Territory and take any other actions reasonably necessary to effect the transfers in subsection (i) above;

(iii) provide Eisai with copies of all Clinical Data and all material correspondence between Pharmavant and such Regulatory Authorities relating to such Regulatory Materials of subsection (i) above;

(iv) unless expressly prohibited by any Regulatory Authority, (A) transfer sponsorship and control to Eisai of all Clinical Trials of Terminated Products being conducted by or on behalf of Pharmavant in the Terminated Territory as of the effective date of termination and (B) continue to conduct such Clinical Trials after the effective date of termination to enable such transfer to be completed without interruption of any such Clinical Trial for up to [***] from the effective date of termination, with the cost of the conduct of such Clinical Trials until the completion of transfer [***];

(v) if requested by Eisai, use Commercially Reasonable Efforts to assign any agreements with Third Parties that relate solely to the Terminated Product in the Terminated Territory which Pharmavant has in place on the effective date of termination with respect to the conduct of Clinical Trials for Terminated Products for the Terminated Territory or the Manufacture of Terminated Products for the Terminated Territory (including agreements with contract manufacturing organizations, contract research organizations, clinical sites and investigators), or, to the extent any such Third Party agreement is not assignable to Eisai, at Eisai's request and expense, use Commercially Reasonable Efforts to arrange to continue to provide such services for a reasonable time after termination (to the extent permitted under the agreement with such Third Party) and to facilitate Eisai' s entry into a replacement agreement with such Third Party for such services;

(vi) [***] solely upon Eisai's request made within [***] from the effective date of termination, transfer to Eisai any supplies of any Terminated Products for the Terminated Territory in the inventory of Pharmavant or any Affiliate or contractor of Roivant Sciences (it being understood that Eisai shall have the right, but not the obligation, to purchase any such Terminated Products), [***];

(vii) provide Eisai with copies of all Know-How included within the license set forth in Section 10.6.1(b) that solely relate to any Terminated Product in the Terminated Territory that have not previously been provided to Eisai; provided, that, with respect to any such Know-How that Pharmavant or its Affiliates maintains as a trade secret, Pharmavant may impose restrictions on Eisai's maintenance and use of such Information or provide Eisai the benefit of such Information without providing or disclosing such Information to Eisai;

(viii) transfer to Eisai all of its right title and interest in all Pharmavant Trademarks that are solely applicable to the Terminated Products in the Terminated Territory; and

(ix) if Pharmavant is Manufacturing or is having Manufactured the Licensed Compound, Licensed Products or any intermediate of such Licensed Products as of the date of termination, Pharmavant shall use Commercially Reasonable Efforts to (A) transfer copies of any documents and materials Controlled by Pharmavant as of the effective date of termination and embodying Pharmavant IP that is at the time of such termination being used by Pharmavant or its Third Party manufacturers to Manufacture the Licensed Compound and any Licensed Products, including but not limited to all suppliers, analytical methods, quality standards, specifications, commercial active pharmaceutical ingredient formula, process chemistry, Manufacturing process descriptions, process flows, cycle times, process parameters, process equipment type and sizes, cleaning methods, commercial active pharmaceutical ingredient samples, master safety data sheets, and stability reports (the "Pharmavant Manufacturing Know-How") to enable the Manufacture of any Terminated Products by Eisai, its Affiliates or any Third Party manufacturer of Eisai, in each case to the extent that such Pharmavant Manufacturing Know-How was not transferred to Pharmavant or such Third Party(ies) by Eisai or its Affiliates or their respective Third Party manufacturers or is otherwise already known to Eisai, its Affiliate or their

respective Third Party manufacturers; and (B) promptly make available to Eisai or any such Third Party manufacturer a reasonable number of appropriately trained personnel to provide, on a mutually convenient timetable, reasonable technical assistance in the transfer of Pharmavant Manufacturing Know-How to Eisai.

(e) The provisions of Article 6 (other than Section 6.1) shall be terminated with respect to the Licensed Product and Eisai shall have the right to assume all Prosecution and Maintenance and enforcement activities under Article 6 with respect to Eisai Patents as to which Pharmavant has assumed the right and authority to Prosecute and Maintain or enforce and Pharmavant will cooperate with Eisai and provide Eisai with reasonable assistance in connection with the transfer of such Prosecution and Maintenance and enforcement activities with respect to such Eisai Patent.

(f) If this Agreement is terminated only with respect to a given country or geographic region or only with respect to a given Licensed Product, then the foregoing effects of termination shall only apply with respect to the terminated country or geographic region or Licensed Product (and, for clarity, the terms and conditions of this Agreement will continue with respect to all other countries and geographic regions and Licensed Products). For the avoidance of doubt, if this Agreement is terminated only with respect to a given country or geographic region or only with respect to a given Licensed Product, Article 6 shall continue to survive and apply after any such termination during the Term on a global basis; provided, that, Eisai's continued Development, Manufacture and Commercialization of the Terminated Products in the Terminated Territory in accordance with this Section 10.6.1(f) will not be subject to Section 6.2.2.

(g) Any and all sublicense agreements entered into by Pharmavant or any of its Affiliates with a Sublicensee pursuant to this Agreement shall survive such termination of this Agreement, except to the extent that: (i) any such Sublicensee is in material breach of this Agreement or such sublicense agreement; or (ii) Eisai elects to grant such Sublicensee a direct license of the sublicensed rights on the same terms applicable to Pharmavant under this Agreement. Pharmavant shall, upon the written request of Eisai, assign any such sublicense (to the extent not terminated pursuant to the preceding sentence) to Eisai or its Affiliates and, upon such assignment, Eisai or its Affiliates, as applicable, shall assume such sublicense.

10.6.2 Termination by Pharmavant for Material Breach or Bankruptcy. Upon termination of this Agreement by Pharmavant in accordance with Section 10.2 or Section 10.4, Pharmavant shall have the right, by providing written notice to Eisai on or before[***] from the effective date of such termination, to have the following apply:

(a) the licenses set forth in Section 2.1 with respect to the Licensed Compound and any Licensed Products in all countries in the Territory shall remain in effect; subject to Pharmavant's continued compliance with the terms of this Agreement; and

(b) the provisions of Article 6 shall remain in effect; provided, however, Eisai's rights in respect of Joint Patents in the Territory shall terminate and Pharmavant shall have the right to assume all Prosecution and Maintenance and enforcement activities under Article 6 with respect to Joint Patents as to which Eisai has assumed the right and authority to Prosecute and Maintain or enforce.

10.7 Surviving Provisions.

10.7.1 Accrued Rights; Remedies. The expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination, and any and all damages or remedies (whether at law or in equity) arising from any breach hereunder, each of which shall survive expiration or termination of this Agreement. Such expiration or termination shall not relieve any Party from obligations which are expressly indicated to survive expiration or termination of this Agreement. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Article 10 are in addition to any other relief and remedies available to either Party under this Agreement, at law, or in equity.

10.7.2 Survival. Without limiting the provisions of Section 10.6 (and any Sections referenced therein), the rights and obligations of the Parties set forth in the following Sections and Articles of this Agreement shall survive the expiration or termination of this Agreement, in addition to those other terms and conditions that are expressly stated to survive termination or expiration of this Agreement: Article 1 (to the extent the definitions are used in other surviving provisions), Section 2.5, Sections 5.2, 5.3, 5.4 and 5.5 (solely in case of termination and solely with respect to amounts accrued prior to termination but not paid), Section 6.1, Sections 6.2.6, 6.3.1, 6.3.4, 6.3.10 and 6.3.11 (respectively, with respect to Joint Patents and Joint IP), Section 6.4, Sections 7.1, 7.2, 7.3, 7.4, 7.5 and 7.10, Section 8.5, Article 9, Section 10.1.2 (solely in case of expiration), Section 10.6 and Section 10.7 and Article 11.

ARTICLE 11
MISCELLANEOUS

11.1 Severability. If one or more of the terms or provisions of this Agreement is held by a court of competent jurisdiction to be void, invalid, or unenforceable in any situation in any jurisdiction, such holding shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the void, invalid, or unenforceable term or provision in any other situation or in any other jurisdiction, and the term or provision shall be considered severed from this Agreement solely for such situation and solely in such jurisdiction, unless the void, invalid, or unenforceable term or provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the void, invalid, or unenforceable term or provision. If the final judgment of such court declares that any term or provision hereof is void, invalid, or unenforceable, the Parties agree to: (a) reduce the scope, duration, area, or applicability of the term or provision or to delete specific words or phrases to the minimum extent necessary to cause such term or provision as so reduced or amended to be enforceable; and (b) make a good-faith effort to replace any void,invalid, or unenforceable term or provision with a valid and enforceable term or provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

11.2 Notices. Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by electronic mail followed by delivery via either of the methods set forth in Sections 11.2(a) and (b), in each case, addressed as set forth below unless changed by notice so given:

If to Pharmavant:

Pharmavant 7 GmbH

[***]

[***]

[***]

If to Eisai:

EISAI CO., LTD.

[***]

With copies to:

Eisai Inc.

[***]

[***]

Any such notice shall be deemed given on the date received, except any notice received after 5:30 p.m. (in the time zone of the receiving Party) on a Business Day or received on a non-Business Day shall be deemed to have been received on the next Business Day. A Party may add, delete, or change the person or address to which notices should be sent at any time upon written notice delivered to the other Parties in accordance with this Section 11.2.

11.3 Assignment. Neither Party may assign this Agreement or assign or transfer any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment or transfer without the other Party's consent (a) to any Affiliate of such Party (including for internal restructuring purposes), provided, that, such transfer shall not adversely affect the other Party's rights and obligations under this Agreement and that such assigning/transferring Party (or its successor entity to the extent such Party is no longer in existence) remains jointly and severally liable with such Affiliate for the performance of this

Agreement or the assigned obligations, or (b) to any Third Party successor-in-interest in connection with a Change of Control Transaction of such Party; provided, that, in each case (a) and (b) that the assigning Party provides written notice to the other Party of such assignment and the assignee shall have agreed in writing to be bound (or is otherwise required by operation of Applicable Law to be bound) in the same manner as such assigning Party hereunder; provided, further, that, no such written notice shall be required in connection with any permitted assignment to any Affiliate of such Party for internal restructuring purposes. In addition, either Party may assign its right to receive proceeds under this Agreement or grant a security interest in such right to receive proceeds under this Agreement to one or more Third Parties providing financing to such Party pursuant to the terms of a security or other agreement related to such financing, including any assignment or transfer to a Third Party of the right to receive payments hereunder in a royalty monetization or similar transaction or for purposes of a royalty financing arrangement. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 11.3 shall be null, void and of no legal effect. For clarity, the provisions of this Section 11.3 shall not apply to or encompass sublicensing of the rights licensed to a Party under this Agreement. [***].

11.4 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by the Parties.

11.5 WAIVER OF JURY TRIAL. EXCEPT AS LIMITED BY APPLICABLE LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, SUIT, PROCEEDING, OR COUNTERCLAIM (WHETHER BASED IN CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE, AND ENFORCEMENT HEREOF. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY ACTION, SUIT, PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

11.6 Choice of Law; Dispute Resolution; Jurisdiction.

11.6.1 Choice of Law. This Agreement shall be governed by, enforced, and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws and excluding the United Nations Convention on Contracts for the International Sales of Goods. Any dispute relating to the inventorship, scope, validity, enforceability or infringement of any patent right shall be governed by and construed and enforced in accordance with the patent laws of the applicable jurisdiction.

11.6.2 Dispute Resolution.

(a) Disputes. The Parties hereby agree that, unless otherwise stipulated in this Agreement, the procedures set forth in this Section 11.6.2 shall be the exclusive mechanism for resolving any dispute (whether in contract, tort, or otherwise), controversy, or claim between the Parties arising out of or in connection with this Agreement, any Party's rights or obligations under this Agreement, breach of this Agreement, or the transactions contemplated by this Agreement (each, a "Dispute").

(b) Notice; Selection of Arbitrators. Either Party may refer any Dispute to arbitration by submitting a written notice of such request to the other Party. Such Dispute shall be finally resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC"), except to the extent the foregoing conflicts with this Section 11.6.2, in which case this Section 11.6.2 shall control. In any such arbitration, (i) the panel will be comprised of one arbitrator chosen by Eisai, one arbitrator chosen by Pharmavant and one arbitrator, who shall act as the chairman of the panel, chosen by the two co-arbitrators; and (ii) if either Party fails or both Parties fail to choose an arbitrator or arbitrators within [***] after receiving notice of commencement of arbitration or if the two arbitrators fail to choose a third arbitrator within [***] after their appointment, then either or both Parties shall immediately request that the ICC select the remaining number of arbitrators to be selected. The arbitrators shall be neutral and independent of the Parties and their respective Affiliates, and may not be current or former directors, officers or employees of the Parties or their respective Affiliates. No party may have any ex parte discussion with any potential arbitrator, except for confirming if such arbitrator is willing and able to serve on the arbitration panel. All arbitrators shall have ten (10) or more years of experience in the pharmaceutical and biotechnology industries, shall have appropriate experience with respect to the matter(s) to be arbitrated, and shall have some experience in mediating or arbitrating issues relating to such agreements. In the case of any Dispute involving an alleged failure to use Commercially Reasonable Efforts, the arbitrators shall, in addition, have experience and expertise in the worldwide development, manufacture and commercialization of pharmaceuticals and the business, legal and scientific considerations related thereto. An arbitrator will be deemed to meet these qualifications unless a Party objects within[***] after the arbitrator is nominated. In the case of a Dispute involving a scientific or accounting matter or determination, an expert having applicable expertise and experience will be selected by the Parties to assist the arbitrators in such scientific or accounting matter or determination (and the arbitrators will select such expert if the Parties cannot agree on such expert within [***] following the selection of the arbitrators). The governing law in Section 11.6.1 shall govern such proceedings. No individual will be appointed to arbitrate a Dispute pursuant to this Agreement unless he or she agrees in writing to be bound by the provisions of this Section 11.6.2. The place of arbitration will be in New York, NY unless otherwise agreed to by the Parties, and the arbitration shall be conducted in English.

(c) Arbitration Hearing. The arbitrators shall set a date for a hearing that shall be held no later than [***] following the appointment of the last of such three (3) arbitrators. The Parties shall have the right to be represented by counsel.

(d) Conduct of Arbitration. No less than [***] prior to the hearing, each Party shall submit the following to the other Party and the arbitration panel: (i) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the panel; (ii) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness; and (iii) a brief in support of such Party's proposed rulings and remedies; provided, that the brief shall not exceed twenty-five (25) pages. This page limitation shall apply regardless of the number of issues raised in the arbitration proceeding. Unless the Parties agree otherwise, no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents. The arbitration panel shall have sole discretion regarding the admissibility of any evidence, except statements made during settlement negotiations and affidavits prepared for the purposes of the hearing shall not be admissible. Within [***] following completion of the hearing, each Party may submit to the other Party and the panel a post-hearing brief in support of its proposed rulings and remedies; provided, that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the proceeding.

(e) Decision of Arbitrators. The arbitrators shall use their best efforts to rule on each disputed issue within [***] after completion of the hearing described in Section 11.6.2(d). The determination of the arbitrators as to the resolution of any Dispute shall be binding and conclusive upon the Parties, absent manifest error. All rulings of the arbitrators shall be in writing and shall be delivered to the Parties as soon as is reasonably possible. Any arbitration award may be entered in and enforced by a court in accordance with Section 11.6.1.

(f) Awards. Any award to be paid by one Party to the other Party as determined by the arbitrators as set forth above under this Section 11.6.2 shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 11.6.2, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in a court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate,the Parties expressly waive any claim for punitive or exemplary damages and agree that the only damages recoverable under this Agreement are compensatory damages.

(g) [***]

(h) Until final resolution of the dispute through judicial determination: (i) this Agreement shall remain in full force and effect; and (ii) the time periods for cure as to any termination shall be tolled. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the Dispute shall be refunded if a court determines that such payments are not due.

11.7 Confidentiality. The existence of a Dispute, any settlement negotiations or any arbitration proceeding, or any submissions or rulings as part of such proceeding, shall be confidential and the arbitrators shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party shall make (or instruct the arbitrators to make) any public announcement with respect to the proceedings or decision of the arbitrators without prior written consent of the other Party. The existence of any Dispute submitted to arbitration, and any award, shall be kept in confidence by the Parties and the arbitrators, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law. Notwithstanding the foregoing, each Party shall have the right to disclose information regarding the arbitration proceeding to the same extent as it may disclose Confidential Information of the other Party under Article 7 above.

11.8 Patent Disputes. Notwithstanding Section 11.6.2, any Dispute, controversy or claim relating to the inventorship, scope, validity, enforceability or infringement of any Patents Covering the Licensed Compound or the Licensed Products shall be submitted to a court of competent jurisdiction in the country in which such patent rights were granted or arose.

11.9 Relationship of the Parties. Eisai and Pharmavant are independent contractors under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute either Party as a partner, agent, or joint venturer of the other Party. No Party will incur any debts or make any commitments for the other Party, except to the extent, if at all, specifically provided herein. Neither Eisai nor Pharmavant, respectively, shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of Eisai and Pharmavant, respectively, or to bind Eisai and Pharmavant, respectively, to any contract, agreement, or undertaking with any Third Party.

11.10 Performance by Affiliates. Subject to the terms and conditions of this Agreement, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

11.11 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to Eisai or Pharmavant from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

11.12 Compliance with Applicable Law. Each Party shall comply with Applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Party (nor any of their Affiliates) shall be required under this Agreement to take any action or to omit to take any action otherwise required to be taken or omitted by it under this Agreement if the taking or omitting of such action, as the case may be, could in its opinion violate any settlement, consent order, corporate integrity agreement, or judgment to which it may be subject from time to time during the Term. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of its Affiliates shall be required to take, or shall be penalized for not taking, any action that such Party reasonably believes is not in compliance with Applicable Law.

11.13 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (as defined below) and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues. The Party affected by such force majeure also shall notify the other Party of the anticipated duration of such force majeure, any actions being taken to avoid or minimize its effect after such occurrence, and shall take reasonable efforts to remove the condition constituting such force majeure. For purposes of this Agreement, “force majeure” means conditions beyond the control of a Party, including an act of God, acts of terrorism, voluntary or involuntary compliance with any regulation, law or order of any government, war, acts of war (whether war be declared or not), labor strike or lockout, civil commotion, pandemic, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. The payment of invoices due and owing hereunder shall in no event be delayed by the payer because of a force majeure event affecting the payer.

11.14 Fees and Expenses. Except as otherwise specified in this Agreement, each Party shall [***] incurred in connection with this Agreement.

11.15 Third Party Beneficiaries. There are no express or implied Third Party beneficiaries hereunder. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party, except for the indemnification rights of the Eisai Indemnitees pursuant to Sections 10.1 and 10.3 and the Pharmavant Indemnitees pursuant to Sections 10.2 and 10.3.

11.16 Entire Agreement. This Agreement, together with the attached Exhibits and Schedules, the Share Purchase Agreement [***] contain the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior express or implied agreements, understandings, and representations, either oral or written, which may have related to the subject matter hereof in any way, including any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date; provided, that, this Agreement shall not supersede the terms and provisions of the [***] applicable to any period prior to the Effective Date.

11.17 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of facsimile by .pdf, .tif, .gif, .jpeg, or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

11.18 Equitable Relief; Cumulative Remedies. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or in equity. The Parties further agree not to raise as a defense or objection to the request or granting of such relief that any breach of this Agreement is or would be compensable by an award of money damages. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

11.19 Interpretation.

11.19.1 Generally. This Agreement has been diligently reviewed by and negotiated by and between the Parties, and in such negotiations each of the Parties has been represented by competent (in-house or external) counsel, and the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

11.19.2 Definitions; Interpretation.

(a) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined and, where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(b) Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(c) The word “will” shall be construed to have the same meaning and effect as the word “shall.”

(d) The words “including,” “includes,” “include,” “for example,” and “*e.g.*,” and words of similar import, shall be deemed to be followed by the words “without limitation.”

(e) The word “or” shall be interpreted to mean “and/or,” unless the context requires otherwise.

(f) The words “hereof,” “herein,” and “herewith,” and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.

(g) Unless the context requires otherwise or otherwise specifically provided: (i) all references herein to Articles, Sections, Schedules, or Exhibits shall be construed to refer to Articles, Sections, Schedules, and Exhibits of this Agreement; and (ii) reference in any Section to any subclauses are references to such subclauses of such Section.

11.19.3 Subsequent Events. Unless the context requires otherwise: (a) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein); (b) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed, or amended; and (c) subject to Section 11.4, any reference herein to any Person shall be construed to include the Person’s successors and assigns.

11.19.4 Headings. Headings, captions, and the table of contents are for convenience only and shall not be used in the interpretation or construction of this Agreement.

11.19.5 Prior Drafts. No prior draft of this Agreement shall be used in the interpretation or construction of this Agreement.

11.19.6 Independent Significance. Although the same or similar subject matter may be addressed in different provisions of this Agreement, the Parties intend that, except as reasonably apparent on the face of the Agreement or as expressly provided in this Agreement, each such provision shall be read separately, be given independent significance, and not be construed as limiting any other provision of this Agreement (whether or not more general or more specific in scope, substance, or content).

11.20 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instruments, and do all such other ministerial, administrative, or similar acts, as may be reasonably necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[Signature Pages Follow]

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date.

EISAI CO, LTD	PHARMAVANT 7 GmbH
By: [***]	By: [***]
Name: [***]	Name: [***]
Title: [***]	Title: [***]

[Signature page to Exclusive License Agreement]

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

[***]

Schedule 1.26

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 1.31

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 1.35-1

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 1.39

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 1.59

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 4.3.1(b)

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

[***]

Schedule 4.4.1

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

Schedule 8.4.1-1

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

Exhibit A

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

Exhibit B

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

Exhibit C-1

Certain confidential information contained in this document, marked by [***], has been omitted because Roivant Sciences, Ltd. (the "Company") has determined that the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

[***]

[***]

Annex 1

Exhibit 31.1

CERTIFICATION

I, Matthew Gline, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Roivant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Reserved];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2022

/S/ MATTHEW GLINE
Matthew Gline
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Richard Pulik, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Roivant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Reserved];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2022

/S/ RICHARD PULIK
Richard Pulik
Principal Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Matthew Gline, Principal Executive Officer of Roivant Sciences Ltd. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 14, 2022

/S/ MATTHEW GLINE
Matthew Gline
Principal Executive Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Richard Pulik, Principal Financial Officer of Roivant Sciences Ltd. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 14, 2022

/S/ RICHARD PULIK
Richard Pulik
Principal Financial Officer

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to the Company, and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.