

**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, 2022
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.)

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

Not Applicable
(Zip Code)

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

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Shares, \$0.000000341740141 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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, 2023, the registrant had 758,427,350 common shares, par value \$0.000000341740141 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 consolidated subsidiaries, 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 may never achieve or maintain profitability.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to successfully market our products, acquire or in-license new products or product candidates, complete the development and commercialization of our products and product candidates and continue to pursue our drug discovery efforts.
- We have limited experience as a commercial company and the marketing and sale of VTAMA[®] (tapinarof) or any future products may be unsuccessful or less successful than anticipated.
- 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.
- We may not be successful in our efforts to acquire, in-license or discover new product candidates.
- We face risks associated with the allocation of capital and personnel across our businesses.
- We face risks associated with the Vant structure.
- The 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 the marketing of our products and our ongoing clinical trials and preclinical studies.
- Clinical trials and preclinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or preclinical studies on the expected timelines, if at all.
- Our approach to the discovery and development of product candidates from our small molecule discovery engine is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from these platforms.
- Certain of our 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 products and product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.
- We depend on the knowledge and skills of our senior leaders and may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- 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, products and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If the patent applications we hold or have in-licensed with respect to our products or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future products or product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our products.
- Patent terms and their scope may be inadequate to protect our competitive position on current and future products and product candidates for an adequate amount of time.

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

- If our performance does not meet market expectations, the price of our securities may decline.
- We have incurred and will continue to incur increased costs as a result of operating as a public company and our management has devoted and will continue to devote a substantial amount of time to new compliance initiatives.
- 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;
- our limited experience as a commercial-stage company and ability to successfully commercialize VTAMA[®] (tapinarof);
- our ability to raise additional capital to fund our business on acceptable terms or at all;
- the receipt of proceeds from the sale of the Myovant Top-Up Shares (as defined below) to Sumitomo (as defined below) in connection with the previously announced acquisition of Myovant Sciences Ltd. by Sumitomo, expected to close in the quarter ended March 31, 2023;
- 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 preclinical 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 preclinical 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 small molecule discovery engine;
- the novelty, complexity and difficulty of manufacturing certain of our products and product candidates, including any manufacturing problems that result in delays in development or commercialization of our products and product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials and/or clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- interim, top-line and/or preliminary data from our clinical trials changing as more data becoming available or data being delayed due to audit and verification processes;
- changes in product manufacturing or formulation that could lead to the incurrence of costs or delays;
- the failure of any third-party we contract with to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable requirements;
- the fact that obtaining approvals for new drugs is 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 our products and product candidates, including, but not limited to, scenarios in which our products and product candidates may cause adverse effects that could delay regulatory approval, discontinue clinical trials, limit the scope of approval or generally result in negative media coverage of us;

- our inability to obtain regulatory approval for a product or product candidate in certain jurisdictions, even if we are able to obtain approval in certain other jurisdictions;
- our ability to effectively manage growth and to attract and retain key personnel;
- any business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally;
- our ability to obtain and maintain patent and other intellectual property protection for our technology, products and product candidates;
- the inadequacy of patent terms and their scope to protect our competitive position;
- the failure to issue (or the threatening of their breadth or strength of protection) or provide meaningful exclusivity for our current and future products and product candidates of our patent applications that we hold or have in-licensed;
- the fact that we do not currently and may not in the future own or license any issued composition of matter patents covering certain of our products and product candidates and our inability to be certain that any of our other issued patents will provide adequate protection for such products and product candidates;
- the fact that our largest shareholders (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 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)

	<u>December 31, 2022</u>	<u>March 31, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,527,437	\$ 2,060,400
Other current assets	118,795	86,123
Total current assets	<u>1,646,232</u>	<u>2,146,523</u>
Property and equipment, net	37,295	25,905
Operating lease right-of-use assets	54,636	61,044
Investments measured at fair value	272,469	325,834
Intangible assets, net	146,105	—
Other assets	46,223	25,823
Total assets	<u>\$ 2,202,960</u>	<u>\$ 2,585,129</u>
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 47,999	\$ 34,583
Accrued expenses	132,359	127,531
Operating lease liabilities	11,863	11,398
Current portion of long-term debt (includes \$27,010 accounted for under the fair value option at December 31, 2022)	37,724	—
Other current liabilities	14,310	10,855
Total current liabilities	<u>244,255</u>	<u>184,367</u>
Liability instruments measured at fair value	80,041	44,912
Operating lease liabilities, noncurrent	54,925	62,468
Long-term debt, net of current portion (includes \$183,510 and \$177,400 accounted for under the fair value option at December 31, 2022 and March 31, 2022, respectively)	375,124	210,025
Other liabilities	21,477	21,923
Total liabilities	<u>775,822</u>	<u>523,695</u>
Commitments and contingencies (Note 11)		
Redeemable noncontrolling interest	—	22,491
Shareholders' equity:		
Common shares, par value \$0.0000000341740141 per share, 7,000,000,000 shares authorized and 726,804,831 and 694,975,965 shares issued and outstanding at December 31, 2022 and March 31, 2022, respectively	—	—
Additional paid-in capital	4,695,386	4,421,614
Accumulated deficit	(3,739,137)	(2,763,724)
Accumulated other comprehensive loss	(729)	(946)
Shareholders' equity attributable to Roivant Sciences Ltd.	<u>955,520</u>	<u>1,656,944</u>
Noncontrolling interests	471,618	381,999
Total shareholders' equity	<u>1,427,138</u>	<u>2,038,943</u>
Total liabilities, redeemable noncontrolling interest and shareholders' equity	<u>\$ 2,202,960</u>	<u>\$ 2,585,129</u>

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		Nine Months Ended December 31,	
	31,		2022	2021
	2022	2021	2022	2021
Revenue, net	\$ 17,052	\$ 24,341	\$ 33,904	\$ 46,063
Operating expenses:				
Cost of revenues	3,586	1,384	8,953	8,507
Research and development (includes \$6,888 and \$17,669 of share-based compensation expense for the three months ended December 31, 2022 and 2021 and \$26,548 and \$47,441 for the nine months ended December 31, 2022 and 2021, respectively)	125,533	137,345	393,358	347,958
Acquired in-process research and development	97,749	16,105	97,749	138,377
Selling, general and administrative (includes \$50,741 and \$53,547 of share-based compensation expense for the three months ended December 31, 2022 and 2021 and \$165,771 and \$440,356 for the nine months ended December 31, 2022 and 2021, respectively)	168,261	115,530	474,996	636,060
Total operating expenses	395,129	270,364	975,056	1,130,902
Loss from operations	(378,077)	(246,023)	(941,152)	(1,084,839)
Change in fair value of investments	(25,948)	38,036	53,277	14,382
Gain on sale of investment	—	—	—	(443,754)
Change in fair value of debt and liability instruments	62,360	23,017	90,032	40,747
Gain on termination of Sumitomo Options	—	—	—	(66,472)
Gain on deconsolidation of subsidiaries	(12,514)	—	(29,276)	—
Other (income) expense, net	(19,898)	(1,029)	(9,567)	2,529
Loss before income taxes	(382,077)	(306,047)	(1,045,618)	(632,271)
Income tax expense	2,819	38	8,983	532
Net loss	(384,896)	(306,085)	(1,054,601)	(632,803)
Net loss attributable to noncontrolling interests	(32,882)	(21,549)	(79,188)	(57,603)
Net loss attributable to Roivant Sciences Ltd.	\$ (352,014)	\$ (284,536)	\$ (975,413)	\$ (575,200)
Net loss per common share—basic and diluted ⁽¹⁾	\$ (0.49)	\$ (0.41)	\$ (1.39)	\$ (0.87)
Weighted average shares outstanding—basic and diluted ⁽¹⁾	713,319,399	686,589,478	703,054,773	662,268,788

(1) Retroactively restated for the stock subdivision as described in Note 8.

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		Nine Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Net loss	\$ (384,896)	\$ (306,085)	\$ (1,054,601)	\$ (632,803)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(8,972)	(2,393)	547	(2,287)
Total other comprehensive (loss) income	(8,972)	(2,393)	547	(2,287)
Comprehensive loss	(393,868)	(308,478)	(1,054,054)	(635,090)
Comprehensive loss attributable to noncontrolling interests	(32,036)	(21,591)	(78,858)	(57,375)
Comprehensive loss attributable to Roivant Sciences Ltd.	<u>\$ (361,832)</u>	<u>\$ (286,887)</u>	<u>\$ (975,196)</u>	<u>\$ (577,715)</u>

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)

	Shareholders' Equity								
	Redeemable Noncontrolling Interest	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount		Income (Loss)	Deficit			
Balance at March 31, 2022	\$ 22,491	694,975,965	\$ —	\$ 4,421,614	\$ (946)	\$ (2,763,724)	\$ 381,999	\$ 2,038,943	
Issuance of subsidiary common shares to the Company	—	—	—	(251)	—	—	251	—	
Issuance of common shares in connection with equity incentive plans and tax withholding payments	—	4,739,781	—	(8,329)	—	—	—	(8,329)	
Issuance of the Company's common shares related to settlement of transaction consideration	—	1,455,719	—	—	—	—	—	—	
Share-based compensation	—	—	—	61,590	—	—	11,204	72,794	
Foreign currency translation adjustment	—	—	—	—	5,966	—	(199)	5,767	
Net loss	—	—	—	—	—	(331,809)	(21,975)	(353,784)	
Balance at June 30, 2022	\$ 22,491	701,171,465	\$ —	\$ 4,474,624	\$ 5,020	\$ (3,095,533)	\$ 371,280	\$ 1,755,391	
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	—	(2,240)	—	—	2,240	—	
Deconsolidation of subsidiary	(22,491)	—	—	—	—	—	—	—	
Issuance of common shares in connection with equity incentive plans	—	1,185,639	—	—	—	—	—	—	
Issuance of the Company's common shares and other consideration for an acquisition	—	2,029,877	—	8,836	—	—	112	8,948	
Share-based compensation	—	—	—	57,415	—	—	4,564	61,979	
Foreign currency translation adjustment	—	—	—	—	4,069	—	(317)	3,752	
Net loss	—	—	—	—	—	(291,590)	(24,331)	(315,921)	
Balance at September 30, 2022	\$ —	704,386,981	\$ —	\$ 4,538,635	\$ 9,089	\$ (3,387,123)	\$ 353,548	\$ 1,514,149	
Issuance of the Company's common shares, net of issuance costs	—	20,000,000	—	94,735	—	—	—	94,735	
Issuance of common shares in connection with equity incentive plans and tax withholding payments	—	2,417,850	—	(982)	—	—	—	(982)	
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	—	(2,822)	—	—	2,822	—	
Issuance of subsidiary common shares, net of issuance costs	—	—	—	19,599	—	—	48,129	67,728	
Subsidiary stock options exercised	—	—	—	260	—	—	177	437	
Deconsolidation of subsidiary	—	—	—	—	—	—	(292)	(292)	
Issuance of subsidiary preferred shares	—	—	—	—	—	—	87,500	87,500	
Share-based compensation	—	—	—	45,961	—	—	11,770	57,731	
Foreign currency translation adjustment	—	—	—	—	(9,818)	—	846	(8,972)	
Net loss	—	—	—	—	—	(352,014)	(32,882)	(384,896)	
Balance at December 31, 2022	\$ —	726,804,831	\$ —	\$ 4,695,386	\$ (729)	\$ (3,739,137)	\$ 471,618	\$ 1,427,138	

	Shareholders' Equity ⁽¹⁾								
	Redeemable Noncontrolling Interest	Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)		Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount			Accumulated Deficit			
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 contribution 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 and cash contribution to majority-owned subsidiaries	—	—	—	(54,779)	—	—	—	54,779	—
Payment of subscription receivable	—	—	—	(40,000)	100,000	—	—	40,000	100,000
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 contribution 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 8.

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (1,054,601)	\$ (632,803)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash acquired in-process research and development	87,749	78,223
Share-based compensation	192,504	487,797
Change in fair value of investments	53,277	14,382
Gain on sale of investment	—	(443,754)
Change in fair value of debt and liability instruments	90,032	40,747
Gain on deconsolidation of subsidiaries	(29,276)	—
Gain on termination of Sumitomo Options	—	(61,472)
Depreciation and amortization	12,904	4,226
Non-cash lease expense	6,009	5,404
Other	(8,066)	(1,161)
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Other current assets	(31,037)	(16,064)
Accounts payable	13,970	3,693
Accrued expenses	5,702	35,576
Deferred consideration liability	—	(50,000)
Operating lease liabilities	(6,814)	(6,171)
Other	3,342	11,117
Net cash used in operating activities	<u>(664,305)</u>	<u>(530,260)</u>
Cash flows from investing activities:		
Cash decrease upon deconsolidation of subsidiaries	(6,706)	—
Proceeds from sale of investment	—	320,170
Milestone payments	(140,136)	—
Purchase of property and equipment	(11,068)	(11,173)
Other	88	—
Net cash (used in) provided by investing activities	<u>(157,822)</u>	<u>308,997</u>
Cash flows from financing activities:		
Proceeds from issuance of the Company's common shares, net of issuance costs paid	94,735	—
Proceeds from Business Combination and PIPE Financing	—	213,424
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	67,727	—
Proceeds from payment of subscription receivable	—	100,000
Proceeds from subsidiary debt financings, net of financing costs paid	159,899	36,400
Repayment of debt by subsidiary	(22,108)	(21,590)
Payment of offering and loan origination costs	(2,250)	(20,265)
Repurchase of equity awards	—	(2,247)
Taxes paid related to net settlement of equity awards	(9,442)	—
Proceeds from exercise of the Company's and subsidiary stock options	569	—
Net cash provided by financing activities	<u>289,130</u>	<u>305,722</u>
Net change in cash, cash equivalents and restricted cash	(532,997)	84,459
Cash, cash equivalents and restricted cash at beginning of period	2,074,034	2,141,676
Cash, cash equivalents and restricted cash at end of period	<u>\$ 1,541,037</u>	<u>\$ 2,226,135</u>
Non-cash investing and financing activities:		
Issuance of the Company's common shares and other consideration for an acquisition	\$ 9,694	\$ —
Other	\$ 7,063	\$ 4,837

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.

VTAMA® (tapinarof) was approved by the United States Food and Drug Administration (“FDA”) in May 2022 for the treatment of plaque psoriasis in adult patients.

The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company’s subsidiaries are wholly owned subsidiaries and majority-owned or controlled subsidiaries. Refer to Note 3, “Investments” for further discussion of the Company’s investments in unconsolidated entities.

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

(B) Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2022, the Company had cash and cash equivalents of approximately \$1.5 billion and its accumulated deficit was approximately \$3.7 billion. For the nine months ended December 31, 2022 and 2021, the Company incurred net losses of approximately \$1.1 billion and \$632.8 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. Through its subsidiary, Dermavant Sciences Ltd., the Company has launched its first commercial product, VTAMA, following approval by the FDA in May 2022.

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals to market its product candidates, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and 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 or discontinue 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 included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2022 filed with the SEC. The unaudited condensed consolidated balance sheet at March 31, 2022 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 nine months ended December 31, 2022 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2023, 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.

(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, 2022 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) Concentrations

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

The Company has long-lived assets in different geographic locations. As of December 31, 2022 and March 31, 2022, a majority of the Company's long-lived assets were located in the United States.

(D) Cash, Cash Equivalents, and Restricted Cash

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

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.

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, 2022	March 31, 2022
Cash and cash equivalents	\$ 1,527,437	\$ 2,060,400
Restricted cash (included in "Other current assets")	3,968	3,903
Restricted cash (included in "Other assets")	9,632	9,731
Cash, cash equivalents and restricted cash	<u>\$ 1,541,037</u>	<u>\$ 2,074,034</u>

(E) Contingencies

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

(F) Inventory

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

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

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

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

(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 3, "Investments."

(H) Intangible Assets, Net

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. The Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 4, "Intangible Assets."

(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 Datavant, (as defined and discussed in Note 3, "Investments"); liability instruments issued, including warrant and earn-out shares liabilities issued in connection with the Company's business combination with MAAC (see Note 12, "Earn-Out Shares, Public Warrants and Private Placement Warrants"); its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus and Sio common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. The shares of common stock of Heracles Parent, L.L.C., the parent entity of Datavant (as defined and discussed in Note 3, "Investments") and liability instruments issued, excluding the Public Warrants (as defined and discussed in Note 12, "Earn-Out Shares, Public Warrants and Private Placement Warrants"), are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. The Public Warrants are publicly traded and therefore are classified as Level 1 as the Public Warrants have a readily determinable fair value. Cash and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant 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) 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. R&D costs primarily consist of costs associated with preclinical studies and clinical trials, including amounts paid to contract research organizations, contract manufacturing organizations, and other third parties that conduct R&D activities on behalf of the Company, as well as employee-related expenses, such as salaries, share-based compensation, and benefits, for employees engaged in R&D activities.

(K) Acquired In-Process Research and Development Expenses

Acquired in-process research and development (“IPR&D”) expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. These expenses were previously included in “Research and development” on the condensed consolidated statements of operations. Prior periods have been revised to conform to the current period presentation.

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

(L) Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for its arrangements, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

License, Milestone, and Other Revenue

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property:* If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.
- *Milestone payments:* At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.

- *Royalties and commercial milestone payments:* For arrangements that include sales-based royalties, including commercial milestone payments based on a pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

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

Product Revenue, Net

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

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

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

More specifically, these adjustments include the following:

- a. **Prompt Pay and Cash Pay Discounts:** The Company generally provides invoice discounts on product sales to its customers for prompt payment and/or cash payment. The Company estimates the amount of such discounts that will be utilized and deducts the amount from its gross product revenues and accounts receivable at the time such revenues are recognized.
- b. **Customer Fees:** The Company pays fees to its customers for account management, data management, and other administrative services. To the extent the services received are distinct from sales of products to the customer, the Company records these payments in selling, general and administrative expenses.
- c. **Chargebacks:** Chargebacks are discounts that occur when contracted customers purchase directly from a wholesaler or specialty distributor. Contracted customers, which currently consist primarily of public health service institutions, federal government entities, pharmaceutical benefit managers, and health maintenance organizations, generally purchase the product at a discounted price. The wholesaler or specialty distributor, in turn, charges back to the Company the difference between the price initially paid by the wholesaler or specialty distributor and the discounted price paid to the wholesaler or specialty distributor by the contracted customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales to contracted customers.

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

Product revenue is included in "Revenue, net" on the accompanying condensed consolidated statements of operations.

Trade Receivables, Net

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in customer credit profiles. The Company reserves against trade receivables for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was de minimis as of December 31, 2022 and March 31, 2022. Trade receivables, net is included in "Other current assets" on the accompanying condensed consolidated balance sheets.

(M) Cost of Revenues

Cost of revenues related to the Company's subscription and service-based revenue recognized for the use of technology developed consists primarily of employee, hosting, and third-party data costs. Following the initial product launch of VTAMA, the Company began to recognize cost of product revenues, which includes the cost of producing and distributing inventories related to product revenue during the respective period, including manufacturing, freight, and indirect overhead costs. Additionally, cost of product revenues may include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. Cost of product revenues through December 31, 2022 is included in "Cost of revenues" on the accompanying condensed consolidated statements of operations.

Note 3—Investments

Investment in Arbutus

In October 2017, pursuant to a subscription agreement entered into by RSL and Arbutus, RSL acquired 16,013,540 shares of common stock of Arbutus and 1,164,000 shares of Arbutus' Series A participating convertible preferred shares, which converted into 22,833,922 shares of Arbutus common stock in October 2021. 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, 2022, RSL held approximately 25% of issued and outstanding shares of Arbutus.

At December 31, 2022 and March 31, 2022, the aggregate fair value of the Company's investment in Arbutus was \$90.5 million and \$115.8 million, respectively. During the three and nine months ended December 31, 2022, the Company recognized an unrealized gain of \$16.3 million and an unrealized loss of \$25.3 million on its investment in Arbutus, respectively, in the accompanying condensed consolidated statements of operations. During the three and nine months ended December 31, 2021, the Company recognized an unrealized loss of \$15.6 million and an unrealized gain of \$21.7 million on its investment in Arbutus, 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, 2022 and March 31, 2022 of \$2.33 and \$2.98, respectively.

Investment in Sio

In February 2020, RSL's ownership interest in Sio fell below 50.0%, and as a result, the Company deconsolidated Sio. The Company accounts for its investment in Sio as an equity method investment accounted for using the fair value option. Due to the Company's significant influence over operating and financial policies, Sio is considered a related party of the Company. At December 31, 2022, RSL held approximately 25% of Sio's issued and outstanding common shares.

At December 31, 2022 and March 31, 2022, the fair value of the Company's investment in Sio was \$8.1 million and \$12.4 million, respectively. During the three and nine months ended December 31, 2022, the Company recognized an unrealized gain of \$2.9 million and an unrealized loss of \$4.3 million on its investment in Sio, respectively, in the accompanying condensed consolidated statements of operations. 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. The fair value of common shares held by the Company was determined using the closing price of Sio's common stock on December 31, 2022 and March 31, 2022 of \$0.44 and \$0.67, respectively.

Investment in Datavant

In April 2020, following an equity raise completed by Datavant Holdings, Inc. ("Datavant") along with a restructuring of Datavant's equity classes, it was determined that RSL no longer controlled Datavant. As such, the Company deconsolidated Datavant as of April 2020. Due to the Company's significant influence over operating and financial policies, Datavant is considered a related party of the Company.

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 in Ciox Parent. As of December 31, 2022, the Company's minority equity interest represented 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 sale of investment 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, 2022 and March 31, 2022, the fair value of the Company's investment was \$172.5 million and \$193.9 million, respectively. During the three and nine months ended December 31, 2022, the Company recognized an unrealized gain of \$7.5 million and an unrealized loss of \$21.4 million on its investment in Datavant, respectively, in the accompanying condensed consolidated statements of operations. During the three and nine months ended December 31, 2021, the Company recognized unrealized losses on its investment of \$4.3 million and \$8.4 million, respectively. 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.

Note 4—Intangible Assets

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

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

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

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

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

	Remaining Weighted Average Estimated Useful Lives (in years)	December 31, 2022
Gross amount	15.9	\$ 151,488
Less: accumulated amortization		(5,383)
Net book value		<u>\$ 146,105</u>

The Company's intangible assets are denominated in currencies other than U.S. dollar and therefore are subject to foreign currency movements.

Amortization expense was \$2.2 million and \$5.2 million for the three and nine months ended December 31, 2022, respectively, and was recorded as part of "Cost of revenues" in the accompanying condensed consolidated statement of operations. Future amortization expense is approximately \$2.3 million for the remainder of the year ended March 31, 2023, \$9.2 million for each of the years ended from March 31, 2024 through March 31, 2027 and \$107.0 million thereafter.

Note 5—Asset Acquisitions and License Agreements

In November 2022, a newly-formed subsidiary ("RVT-3101 Vant") entered into a license and collaboration agreement with Pfizer, Inc. ("Pfizer"), pursuant to which Pfizer granted RVT-3101 Vant an exclusive license to RVT-3101, a fully human monoclonal antibody targeting TL1A. Under the license, RVT-3101 Vant will be responsible for funding the worldwide development of RVT-3101 in ulcerative colitis and in additional inflammatory and fibrotic diseases and holds commercialization rights in the US and Japan. Pfizer will maintain commercialization rights and rights to revenue outside of the US and Japan. At closing, the Company contributed \$45.0 million in cash to RVT-3101 Vant and committed to contribute or raise additional capital that is non-dilutive to Pfizer.

In addition, Pfizer granted RVT-3101 Vant an exclusive option to collaborate with Pfizer on a next-generation TL1A directed antibody which recently entered Phase 1. The option provides RVT-3101 Vant the right to enter into an agreement for global development with a 50/50 cost share as well as co-commercialization with Pfizer prior to Phase 2.

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 \$87.7 million, primarily consisting of preferred stock issued to Pfizer, which represents a dilution-protected 25% equity interest in RVT-3101 Vant. The acquired rights, which included the licensed rights, starting materials and in-process inventory, and the exclusive option to collaborate with Pfizer on a next-generation TL1A directed antibody, represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded \$87.7 million as acquired in-process research and development expense in the accompanying condensed consolidated statements of operations for the three and nine months ended December 31, 2022.

RVT-3101 Vant is obligated to pay a mid-single-digit royalty on aggregate net sales of its licensed products in RVT-3101 Vant's territory.

Note 6—Certain Balance Sheet Components

(A) Other Current Assets

Other current assets at December 31, 2022 and March 31, 2022 consisted of the following (in thousands):

	December 31, 2022	March 31, 2022
Prepaid expenses	\$ 69,507	\$ 53,370
Trade receivables, net	27,967	3,878
Restricted cash	3,968	3,903
Income tax receivable	1,487	2,854
Other	15,866	22,118
Total other current assets	<u>\$ 118,795</u>	<u>\$ 86,123</u>

(B) Accrued Expenses

Accrued expenses at December 31, 2022 and March 31, 2022 consisted of the following (in thousands):

	December 31, 2022	March 31, 2022
Research and development expenses	\$ 56,327	\$ 66,188
Compensation-related expenses	41,916	44,262
Sales allowances	16,426	—
Other expenses	17,690	17,081
Total accrued expenses	<u>\$ 132,359</u>	<u>\$ 127,531</u>

(C) Other Current Liabilities

Other current liabilities at December 31, 2022 and March 31, 2022 consisted of the following (in thousands):

	December 31, 2022	March 31, 2022
Deferred revenue	\$ 7,796	\$ 10,147
Income tax payable	5,637	708
Other	877	—
Total other current liabilities	<u>\$ 14,310</u>	<u>\$ 10,855</u>

Note 7—Long-Term Debt**Dermavant*****Funding Agreement with NovaQuest***

In connection with Dermavant’s acquisition of tapinarof from GSK pursuant to an asset purchase agreement (the “GSK Agreement”), Dermavant and NovaQuest Co-Investment Fund VIII, L.P. (“NovaQuest”) entered into a funding agreement (the “NovaQuest Agreement”). Pursuant to the NovaQuest Agreement, Dermavant borrowed \$100.0 million in August 2018 and \$17.5 million in October 2018.

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

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, 2022 and March 31, 2022, the fair value of the debt was \$210.5 million and \$177.4 million, respectively. Refer to Note 13, “Fair Value Measurements” for additional details regarding the fair value measurement.

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

	December 31, 2022	March 31, 2022
Fair value of long-term debt	\$ 210,520	\$ 177,400
Less: current portion	(27,010)	—
Total long-term debt, net	\$ 183,510	\$ 177,400

Credit Facility with XYQ Luxco

In May 2021, Dermavant entered into 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, 2022. In connection with the funding of the Credit Facility, Dermavant issued a warrant to XYQ Luxco to purchase 1,199,072 common shares of Dermavant at an exercise price of \$0.01 per common share.

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

	December 31, 2022	March 31, 2022
Principal amount	\$ 40,000	\$ 40,000
Exit fee	5,000	5,000
Less: unamortized discount and debt issuance costs	(10,752)	(12,375)
Total debt, net	34,248	32,625
Less: current portion	—	—
Total long-term debt, net	\$ 34,248	\$ 32,625

Revenue Interest Purchase and Sale Agreement

In May 2021, Dermavant, as seller, entered into a \$160.0 million revenue interest purchase and sale agreement (the “RIPSA”) for its investigational product tapinarof with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, Dermavant is obligated to pay royalties based on a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States, up to a cap of \$344.0 million, in exchange for the \$160.0 million in committed funding, which was paid to Dermavant in June 2022 following the approval of tapinarof by the FDA.

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

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

	December 31, 2022
Carrying balance	\$ 173,048
Less: unamortized issuance costs	(4,968)
Total debt, net	168,080
Less: current portion	(10,714)
Total long-term debt, net	\$ 157,366

Note 8—Shareholders’ Equity

(A) RSL Common Stock

On September 30, 2021 in connection with the closing of the Business Combination, the Company 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.

Additionally, in connection with the closing of the Business Combination, the Company adjusted its authorized share capital to equal 7,000,000,000 common shares, par value \$0.000000341740141 per share. Each common share has the right to one vote. The holders of 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.

(B) At-the-Market Equity Offering Program

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

As of December 31, 2022, the Company had \$400.0 million of remaining capacity available under the ATM Facility.

The Company had previously entered into a committed equity facility (the "Cantor Facility") with an affiliate of Cantor Fitzgerald & Co. ("Cantor") on February 14, 2022. Under the terms of the Cantor Facility, Cantor 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. In connection with the Company's entry into the Sales Agreement with Cowen, the Company elected to terminate the Cantor Facility, effective as of October 5, 2022.

(C) Underwritten Primary and Secondary Public Offering of Common Shares

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

(D) Disposal of Cytovant

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

(E) Consolidated Vant Equity Transaction

Immunovant

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

Note 9—Share-Based Compensation

(A) 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, and the Roivant Sciences Ltd. Amended and Restated 2015 Restricted Stock Unit 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. At December 31, 2022, a total of 11,164,165 common shares were available for future grants under the RSL 2021 EIP.

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, 2022 is as follows:

	Number of Options
Options outstanding at March 31, 2022	80,364,904
Granted	74,708,623
Exercised	(57,812)
Forfeited/Canceled	(384,690)
Options outstanding at December 31, 2022	<u>154,631,025</u>
Options exercisable at December 31, 2022	<u>55,632,730</u>

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, 2022 is as follows:

	Number of Shares
Non-vested balance at March 31, 2022	21,956,749
Granted	11,154,557
Vested	(5,761,045)
Forfeited	(5,196,487)
Non-vested balance at December 31, 2022	<u>22,153,774</u>

Capped Value Appreciation RightsMarch 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. On March 30, 2022, the Company amended the outstanding CVARs that were granted in March 2020. Pursuant to the amendment, in the event any CVARs have satisfied the time-based service and liquidity event vesting requirements (“service-vested CVARs”) but have not satisfied the applicable hurdle price on an applicable measurement date, then such CVARs will be deemed to remain outstanding and the applicable award holder will be provided the right to earn such CVARs if the hurdle price is satisfied on subsequent annual “hurdle measurement dates” prior to the original expiration date of the CVARs, being March 31, 2026. The “hurdle measurement dates” are March 30 of each of years 2023 through 2026. If the hurdle price is not satisfied on any such subsequent annual hurdle measurement date prior to the expiration date of the CVARs, then the CVARs will be forfeited in their entirety on the expiration date. As of December 31, 2022, there are 7,884,620 non-service-vested CVARs and 24,127,376 service-vested CVARs relating to the March 2020 grants. The hurdle price was not satisfied for these service-vested CVARs and as such they remain outstanding.

November 2021 CVAR Grants

Activity for CVARs under the RSL 2021 EIP for the nine months ended December 31, 2022 is as follows:

	Number of CVARs
Non-vested balance at March 31, 2022	6,285,250
Vested	(2,296,116)
Forfeited	(380,113)
Non-vested balance at December 31, 2022	<u>3,609,021</u>

(B) 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 \$13.7 million and \$37.8 million for the three and nine months ended December 31, 2022, respectively, and \$12.9 million and \$32.4 million for the three and nine months ended December 31, 2021, respectively, related to subsidiary EIPs.

Note 10—Income Taxes

The Company's effective tax rate for the three and nine months ended December 31, 2022 was (0.7)% and (0.9)%, respectively, and the effective tax rate for the three and nine months ended December 31, 2021 was (0.01)% and (0.1)%, 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 11—Commitments and Contingencies

(A) Commitments

In conjunction with the purchase agreement of tapinarof between the Company's subsidiary, Dermavant, and GSK, Dermavant entered into a clinical supply agreement for which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during the Company's clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and price. The commercial supply agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, Dermavant and GSK amended the terms of the clinical supply and commercial supply agreements which released GSK of certain commitments to supply tapinarof and released Dermavant of certain commitments to purchase tapinarof in exchange for a supplementary fee. Other supply and purchase commitments under the agreements remain in effect. In addition, Dermavant and Thermo Fisher Scientific ("TFS") entered into a Commercial Manufacturing and Supply Agreement for which TFS will provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. As of December 31, 2022, the minimum purchase commitment related to these agreements is estimated to be approximately \$34.1 million.

In November 2021, the Company's subsidiary, Immunovant, entered into a Product Service Agreement with Samsung Biologics Co., Ltd. ("Samsung") by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. As of December 31, 2022, the minimum purchase commitment related to this agreement is estimated to be approximately \$33.1 million.

In May 2021, the Company entered into a master subscription agreement with Palantir Technologies Inc. ("Palantir") for access to Palantir's proprietary software for a five-year period. As of December 31, 2022, the remaining minimum payments for this software subscription are \$30.0 million.

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.

The Company also has commitments relating to its long-term debt and operating leases. Refer to Note 7, "Long-Term Debt" for further information. There have been no material changes to the commitments relating to the Company's operating leases during the nine months ended December 31, 2022 outside the ordinary course of business. For further information regarding the Company's lease commitments, refer to Note 12, "Leases" in the Company's Annual Report on Form 10-K for the year ended March 31, 2022.

(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.

Immunovant Securities Litigation

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 sought 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, as amended, on behalf of a putative class consisting of those who purchased or otherwise acquired Immunovant's securities pursuant and/or traceable to Immunovant's follow-on public offering on or about September 2, 2020. On March 15, 2022, the lead plaintiff filed a further amended complaint. On May 27, 2022, the defendants, including the Company, filed motions to dismiss that amended complaint. The fully briefed motion to dismiss, including defendants' opening briefs, lead plaintiff's opposition and defendants' replies were filed with the court on September 9, 2022. No hearing date has been set. The Company intends to continue 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.

Acuitas Declaratory Judgment Action

In March 2022, Acuitas Therapeutics Inc. filed a lawsuit in the U.S. District Court for the Southern District of New York against two of the Company's affiliates, Genevant and Arbutus, seeking a declaratory judgment that U.S. Patents 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127, 9,504,651, 9,518,272 and 11,141,378 are not infringed by the manufacture, use, offer for sale, sale or importation into the United States of COMIRNATY, Pfizer's and BioNTech's vaccine for COVID-19 and are otherwise invalid. On September 6, 2022, Acuitas filed a First Amended Complaint. In response, on October 4, Genevant and Arbutus filed a motion to dismiss the first amended complaint for lack of a controversy and supporting brief. Briefing on this motion was completed in mid-November. Each of Genevant and Arbutus intend to continue to vigorously defend the case.

(C) Indemnification Agreements

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain. The Company also indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits. The maximum amount of potential future indemnification is unlimited; however, the Company currently maintains director and officer liability insurance, which may cover certain liabilities arising from the Company's obligation to indemnify its directors. To date, the Company has not incurred any material costs related to these indemnification obligations and has not accrued any liabilities related to such obligations in the condensed consolidated financial statements as of December 31, 2022 and March 31, 2022.

Note 12—Earn-Out Shares, Public Warrants and Private Placement Warrants

Earn-Out Shares

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

- a. 2,033,591 common shares to Patient Square Capital LLC (the "MAAC Sponsor") and 10,000 common shares issued to each of MAAC's independent directors (collectively, the "20% Earn-Out Shares"), which will vest if the closing price of the Company's common shares is greater than or equal to \$15.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).
- b. 1,016,796 common shares issued to the MAAC Sponsor and 5,000 common shares issued to each of MAAC's independent directors (collectively, the "10% Earn-Out Shares" and, together with the 20% Earn-Out Shares, the "Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of the Company's common shares is greater than or equal to \$20.00 over any twenty out of thirty trading day period during the Vesting Period (as defined below).

- c. The remaining number of common shares issued to the MAAC Sponsor and each of MAAC's independent director are not subject to the vesting conditions described above (the "Retained Shares").

The Vesting Period commenced on November 9, 2021 and ends no later than September 30, 2026 (the "Vesting Period"). The Vesting Period will, if a definitive purchase agreement with respect to a Sale (as defined in the Sponsor Support Agreement) is entered into on or prior to the end of such period, be extended to the earlier of one day after the consummation of such Sale and the termination of such definitive transaction agreement, and if a Sale occurs during such Vesting Period, then all of the Earn-Out Shares unvested as of such time will automatically vest immediately prior to the consummation of such Sale. If any Earn-Out Shares have not vested on or prior to the end of such Vesting Period, then such Earn-Out Shares will be forfeited.

The Earn-Out Shares require liability classification and are classified as "Liability instruments measured at fair value" on the 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. As of December 31, 2022, no Earn-Out Shares have vested.

Public Warrants and Private Placement Warrants

Immediately following the Business Combination, the Company had 10,214,365 outstanding warrants for the purchase of one of the Company's common shares, which were held by the MAAC Sponsor at an exercise price of \$11.50 (the "Private Placement Warrants"), and 20,535,896 outstanding warrants for the purchase of one of the Company's common shares, which were held by MAAC's shareholders at an exercise price of \$11.50 (the "Public Warrants"). Pursuant to the agreement governing these warrants, the Private Placement Warrants and Public Warrants became exercisable 30 days following the completion of the Business Combination and 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 the Company's common stock 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 the MAAC Sponsor or its permitted transferees, the Private Placement Warrants will be redeemable by the Company in all redemption scenarios and exercisable by the holders on the same basis as the Public Warrants.

The Private Placement Warrants and Public Warrants require liability classification 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. As of December 31, 2022, 60,021 Public Warrants have been exercised and none redeemed.

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, 2022 and March 31, 2022, by level, within the fair value hierarchy (in thousands):

	As of December 31, 2022				As of March 31, 2022			
	Level 1	Level 2	Level 3	Balance as of December 31, 2022	Level 1	Level 2	Level 3	Balance as of March 31, 2022
Assets:								
Money market funds	\$ 1,187,904	\$ —	\$ —	\$ 1,187,904	\$ 1,297,844	\$ —	\$ —	\$ 1,297,844
Investment in Datavant Class A units	—	—	172,511	172,511	—	—	193,963	193,963
Investment in Sio common shares	8,081	—	—	8,081	12,447	—	—	12,447
Investment in Arbutus common shares	90,515	—	—	90,515	115,765	—	—	115,765
Other investment	1,362	—	—	1,362	3,659	—	—	3,659
Total assets at fair value	\$ 1,287,862	\$ —	\$ 172,511	\$ 1,460,373	\$ 1,429,715	\$ —	\$ 193,963	\$ 1,623,678
Liabilities:								
Debt issued by Dermavant to NovaQuest	\$ —	\$ —	\$ 210,520	\$ 210,520	\$ —	\$ —	\$ 177,400	\$ 177,400
Liability instruments measured at fair value ⁽¹⁾	39,723	—	40,318	80,041	18,019	—	26,893	44,912
Total liabilities at fair value	\$ 39,723	\$ —	\$ 250,838	\$ 290,561	\$ 18,019	\$ —	\$ 204,293	\$ 222,312

- (1) At December 31, 2022, Level 1 includes the fair value of the Public Warrants of \$39.7 million, and Level 3 includes the fair value of the Earn-Out Shares of \$17.1 million, Private Placement Warrants of \$20.1 million, and other liability instruments issued of \$3.1 million. At March 31, 2022, Level 1 includes the fair value of the Public Warrants of \$18.0 million, and Level 3 includes the fair value of the Earn-Out Shares of \$9.2 million, Private Placement Warrants of \$9.1 million, and other liability instruments issued of \$8.6 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, 2022.

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, 2022 and 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	\$	<u>215,681</u>
Balance at March 31, 2022	\$	193,963
Changes in fair value of investment in Datavant, included in net loss		(21,452)
Balance at December 31, 2022	\$	<u>172,511</u>

The changes in fair value of the Level 3 liabilities during the nine months ended December 31, 2022 and 2021 were as follows (in thousands):

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 Sumitomo Options		(61,472)
Balance at December 31, 2021	\$	<u>224,402</u>
Balance at March 31, 2022	\$	204,293
Fair value of liability instrument issued		248
Payments related to long-term debt		(22,031)
Changes in fair value of debt and liability instruments, included in net loss		68,328
Balance at December 31, 2022	\$	<u>250,838</u>

Investment in Datavant

The Company elected the fair value option to account for the investment in Datavant. The estimate of fair value for this investment was determined using the income approach and implementation of the option pricing method (“OPM”). The OPM allows for the allocation of a company’s equity value among the various equity capital owners (preferred and common shareholders). The OPM uses the preferred shareholders’ liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date. The fair value was calculated using significant unobservable inputs including the following:

Input	Point Estimate Used	
	As of December 31, 2022	As of March 31, 2022
Volatility	100.0%	110.0%
Risk-free rate	4.32%	1.62%

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of December 31, 2022 and March 31, 2022 represents the fair value of amounts payable to NovaQuest calculated using the Monte Carlo simulation method under the income approach determined by using probability assessments of the expected future payments through 2032. The future payments are based on significant inputs that are not observable in the market which are subject to remeasurement at each reporting date. The estimates of fair value may not be indicative of the amounts that could ultimately be paid by Dermavant to NovaQuest.

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 12, “Earn-Out Shares, Public Warrants and Private Placement Warrants” for additional details. Significant unobservable inputs used to calculate the fair value of the Earn-Out Shares included the following:

Input	Point Estimate Used	
	As of December 31, 2022	As of March 31, 2022
Volatility	78.4%	82.3%
Risk-free rate	4.13%	2.43%

As of December 31, 2022, the fair value of the Earn-Out Shares was \$17.1 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 12, “Earn-Out Shares, Public Warrants and Private Placement Warrants” 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, 2022	As of March 31, 2022
Volatility	58.2%	56.5%
Risk-free rate	4.13%	2.43%
Term (in years)	3.75	4.50

As of December 31, 2022, the fair value of the Private Placement Warrants was \$20.1 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,	
	2022	2021	2022	2021
Interest income	\$ (10,249)	\$ (66)	\$ (17,900)	\$ (199)
Interest expense	8,446	1,501	19,393	5,566
Other income	(18,095)	(2,464)	(11,060)	(2,838)
Total	\$ (19,898)	\$ (1,029)	\$ (9,567)	\$ 2,529

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 stock 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, 2022 and 2021, potentially dilutive securities were as follows:

	December 31, 2022	December 31, 2021
Stock options and performance stock options	154,631,025	80,754,174
Restricted stock units and performance stock units (non-vested)	22,153,774	22,587,681
March 2020 CVARs ⁽¹⁾	32,011,996	32,447,626
November 2021 CVARs (non-vested)	3,609,021	6,317,350
Restricted common stock (non-vested)	730,522	988,540
Earn-Out Shares (non-vested)	3,080,387	3,080,387
Private Placement Warrants	10,214,365	10,214,365
Public Warrants	20,475,875	20,535,896
Other stock based awards and instruments issued	6,178,990	5,134,088

(1) Refer to Note 9, “Share-Based Compensation” for details regarding settlement of CVARs.

Note 16—Subsequent Events

In February 2023, the Company completed an underwritten public offering of 30,666,665 common shares of RSL (including 3,999,999 common shares issued and sold upon the full exercise of the underwriters’ option to purchase additional shares) at a price to the public of \$7.50 per share. Total gross proceeds from the offering, including the option exercise, before deducting underwriting discounts and commissions and other offering expenses were \$230 million.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our (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, 2022, included in our Annual Report on Form 10-K, filed with the SEC on June 28, 2022 (the “Form 10-K”). Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Roivant’s actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. Please see “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 computational tools as well as the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is 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 leading computational physics and machine learning (“ML”) capabilities for *in silico* drug design.

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

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology and oncology, and modalities, including biologics, topicals and bifunctional small molecules. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately \$1.5 billion in our publicly-traded Vants as of December 31, 2022 (inclusive of the value of certain shares of Myovant Sciences Ltd. as to which Roivant has a return right under certain circumstances (the “Myovant Top-Up Shares”). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

- commercially launched VTAMA[®] (tapinarof) cream 1% for the treatment of plaque psoriasis in adults;
- conducted nine international Phase 3 trials, the last eight of which have been successful;
- consummated a \$3 billion upfront partnership with Sumitomo Pharma (“Sumitomo”);
- received six FDA approvals for drugs developed by Vants launched by Roivant, including VTAMA and four drugs that received FDA approval after their transfer to Sumitomo;
- built a broad and differentiated pipeline of drugs and drug candidates ranging from early discovery to commercial stage; and
- launched Roivant Discovery, our small molecule discovery engine, consisting of a collection of advanced computational physics capabilities, integrated with an in-house wet lab facility.

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

Product/Product Candidate	Indication	Vant	Modality	Phase
VTAMA® (tapinarof)	Psoriasis	Dermavant	Topical	Commercial
VTAMA® (tapinarof)	Atopic Dermatitis	Dermavant	Topical	Phase 3†
RVT-3101	Ulcerative Colitis	RVT-3101 Vant	Biologic	Phase 2
RVT-3101	Crohn's Disease	RVT-3101 Vant	Biologic	Phase 2
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	Phase 3†
Brepocitinib	Systemic Lupus Erythematosus	Priovant	Small Molecule	Phase 2†
Brepocitinib	Other Indications	Priovant	Small Molecule	Phase 2
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 3†
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 3†
Batoclimab	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2†
Batoclimab	Graves' Disease	Immunovant	Biologic	Phase 2
IMVT-1402	Numerous Indications	Immunovant	Biologic	Phase 1
Namnilumab	Sarcoidosis	Kinevant	Biologic	Phase 2
RVT-2001	Transfusion-Dependent Anemia in Patients with Lower-Risk MDS	Hemavant	Small Molecule	Phase 1/2

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

† Indicates registrational or potentially registrational trials.

Our small molecule discovery engine, Roivant Discovery, is powered by leading computational physics and machine learning (“ML”) capabilities for *in silico* drug design. It is organized into a number of Vants, each focused on a different modality or discovery technology:

- Proteovant: Discovery and development of targeted protein degraders
- VantAI: Next generation geometric deep learning for industry leading ternary complex modeling and evolutionarily guided rational molecular glue design
- Covant: Emulating biology, we harness covalency to allosterically imprint and prosecute hard-to-drug targets.
- Psivant: Using QUAISAR, our computational physics platform, to drive small molecule therapeutic discovery for de-risked biological targets

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of December 31, 2022.

Vant	Roivant Ownership	
	Basic ¹	Fully Diluted ²
Dermavant	100%	85%
RVT-3101 Vant	75%	75%
Immunovant	57% ³	51% ³
Priovant	75%	70%
Proteovant	60%	54%
Genevant	83%	65%
Kinevant	88%	82%
Hemavant	100%	99%
Affivant	100%	97%
Covant	100%	100%
Psivant	100%	100%
Arbutus	25% ³	23% ³
Lokavant	64%	57%
Datavant	*	*

1. Basic ownership refers to Roivant's percentage ownership of the issued and outstanding common and preferred shares (if applicable) of the entity.
2. Fully diluted ownership refers to Roivant's percentage ownership of all outstanding equity interests of the entity, including unvested RSUs as well as options and warrants, in each case whether vested or unvested.
3. Denotes entities that are publicly traded.

* As of December 31, 2022, the Company's minority equity interest in Datavant represented approximately 17% of the outstanding Class A units. Datavant's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted. For more information on Roivant's ownership interest in Datavant, please refer to Note 3 to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

We have a robust calendar of potential near-term catalysts, including the items set forth below.

Program	Vant	Catalyst	Expected Timing
VTAMA® (tapinarof)	Dermavant	Updates on commercial launch of VTAMA in psoriasis	Ongoing
Roivant pipeline growth	Roivant	New mid/late-stage in-licensing announcements	Ongoing
LNP platform	Genevant	Updates to LNP patent litigation	Ongoing
Roivant Discovery	Roivant	Updates on discovery programs and technology	Ongoing
VTAMA® (tapinarof)	Dermavant	Topline data from Phase 3 trials in atopic dermatitis	March 2023 & May 2023
RVT-3101	RVT-3101 Vant	Final data from Phase 2B trial in ulcerative colitis	1H 2023
IMVT-1402	Immunovant	Initial data from Phase 1 trial	Mid-2023
Brepocitinib	Priovant	Topline data from potentially registrational Phase 2B trial in systemic lupus erythematosus	4Q 2023
Batoclimab	Immunovant	Initial data from Phase 2 trial in Graves' disease	2H 2023
RVT-2001	Hemavant	Data from RVT-2001 Phase 1/2 trial in lower-risk myelodysplastic syndrome	2H 2023
Batoclimab	Immunovant	Initial data from pivotal Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	1H 2024
Namilumab	Kinevant	Topline data from Phase 2 trial in sarcoidosis	1H 2024
Batoclimab	Immunovant	Topline data from Phase 3 trial in myasthenia gravis	2H 2024
Batoclimab	Immunovant	Topline data from Phase 3 trials in thyroid eye disease	1H 2025
Brepocitinib	Priovant	Topline data from Phase 3 trial in dermatomyositis	2025

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

Recent Developments

- Roivant:** In February, Roivant completed an upsized primary equity offering for \$230 million in gross proceeds, including the exercise in full of the underwriters' overallotment option following strong investor demand. The company plans to use the net proceeds from the offering principally to fund additional studies of RVT-3101, including the initiation of Phase 3 development in ulcerative colitis and Phase 2 development in other indications. Roivant had consolidated cash, cash equivalents and restricted cash of \$1.5 billion at December 31, 2022, or \$1.9 billion after giving effect to the receipt of the anticipated proceeds from the sale of Myovant equity rights to Sumitomo and the net proceeds from the offering, supporting cash runway into the second half of calendar year 2025.
- Dermavant:** Through February 10, 2023, nearly 100,000 VTAMA prescriptions have been written by approximately 8,600 unique prescribers, based on IQVIA data. For the quarter ended December 31, 2022, Roivant reported VTAMA net product revenue of \$9.2 million, representing a gross-to-net yield of approximately 18%. There has been significant progress on payor coverage with the majority of commercial lives, 57%, now covered. Tapinarof Phase 3 trials in atopic dermatitis, ADORING 1 and ADORING 2, are fully enrolled.
- Immunovant:** In November 2022, Immunovant initiated a Phase 3 trial to evaluate batoclimab as a treatment for Thyroid Eye Disease (TED). Additionally, in December 2022, IMVT initiated a pivotal Phase 2b trial of batoclimab as a treatment for chronic inflammatory demyelinating polyneuropathy (CIDP).

- **RVT-3101:** In December, Roivant announced a collaboration with Pfizer to develop and commercialize RVT-3101, a potentially first in class, fully human monoclonal antibody that blocks tumor necrosis factor-like ligand 1A (TL1A). In January, Roivant announced data from the induction period of TUSCANY-2, a large 245-patient global Phase 2b study of RVT-3101 against placebo for the treatment of ulcerative colitis. TUSCANY-2 is a 52-week study, with a 12-week induction period comparing different doses of RVT-3101 against placebo, and a 40-week chronic therapy period during which all subjects receive RVT-3101. In the induction period of the TUSCANY-2 study, RVT-3101 demonstrated statistically significant and clinically meaningful efficacy at each dose tested. At the expected Phase 3 dose, 31% of patients achieved clinical remission (modified Mayo) ($p=0.01$, 20% delta compared to 12% placebo) and 40% of patients achieved endoscopic improvement ($p=0.01$, 22% delta compared to 19% placebo). At the expected Phase 3 dose, among patients who were positive for a biomarker that was prospectively defined in TUSCANY-2, clinical remission (modified Mayo) and endoscopic improvement rates were 40% ($p=0.02$, 30% delta compared to 10% placebo) and 56% ($p=0.0005$, 46% delta compared to 10% placebo), respectively. Approximately 60% of patients were identified as positive for this biomarker. Across all doses and patient groups, RVT-3101 was well tolerated and showed a favorable safety profile.

Impact of COVID-19

The COVID-19 pandemic continues to present global public health and economic challenges that may impact our business. Although some of our clinical development timelines have been impacted by delays related to the COVID-19 pandemic, we have not experienced a material financial impact on our business and operations as a result of the pandemic. However, the impact on our future operations and financial results will largely depend on future developments related to COVID-19, which are highly uncertain and cannot be accurately predicted, such as the continued emergence of new variants of COVID-19, the ultimate duration of the pandemic, the continuing impact of the pandemic on financial markets and the global economy, travel restrictions and other preventative measures implemented 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 manage the pandemic, including the availability and effectiveness of vaccines, and vaccine booster shots.

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

With the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022, we began to recognize product revenues after our initial product launch. We record product revenue net of estimated chargebacks, discounts, rebates, returns, and other allowances associated with the respective sales. Revenue, net also includes the recognition of upfront payments received in connection with license agreements as well as revenue generated by subscription and service-based fees.

Cost of revenues

We began to recognize cost of product revenues after the initial launch of VTAMA in May 2022. Cost of product revenues includes the cost of producing and distributing inventories related to product revenue during the respective period, including manufacturing, freight, and indirect overhead costs. Additionally, milestone payments made in connection with regulatory approvals and sales-based milestones are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Our cost of revenues also relates to subscription and service-based revenue recognized for the use of technology developed and consists primarily of employee, hosting, and third-party data costs.

Research and development expenses

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

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

Research and development activities will continue to be central to our business model. We anticipate that our research and development expenses will increase for the foreseeable future as we advance our product candidates and our recently in-licensed assets, including RVT-3101, through preclinical studies and clinical trials, as well as acquire or discover new product candidates. We expect higher employee-related expenses, including share-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity.

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

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

The successful development of our product candidates is highly uncertain, and we cannot reasonably estimate the costs that will be necessary to complete the remainder of the development of our product candidates. In addition, the probability of success for our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability.

Acquired in-process research and development expenses

Acquired in-process research and development (“IPR&D”) expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. These expenses were previously recorded in “Research and development” on the condensed consolidated statements of operations. Prior periods have been revised to conform to the current period presentation.

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

Selling, general and administrative expenses

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

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

Change in fair value of investments

Change in fair value of investments primarily includes the unrealized (gain) loss on equity investments in publicly-traded companies, including Arbutus Biopharma Corporation (“Arbutus”) and Sio Gene Therapies Inc. (“Sio”), 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.

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. to NovaQuest Co-Investment Fund VIII, L.P. (the “NovaQuest Facility”), and other liability instruments, including warrant and earn-out share liabilities issued in connection with our business combination (the “Business Combination”) with Montes Archimedes Acquisition Corp. (“MAAC”), a special purpose acquisition company.

Gain on deconsolidation of subsidiaries

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

Other (income) expense, net

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

Income tax expense

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

Net loss attributable to noncontrolling interests

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

Results of Operations**Comparison of the three and nine months ended December 31, 2022 and 2021**

The following table sets forth our results of operations for the three months ended December 31, 2022 and 2021:

	Three Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
Revenue, net	\$ 17,052	\$ 24,341	\$ (7,289)
Operating expenses:			
Cost of revenues	3,586	1,384	2,202
Research and development	125,533	137,345	(11,812)
Acquired in-process research and development	97,749	16,105	81,644
Selling, general and administrative	168,261	115,530	52,731
Total operating expenses	<u>395,129</u>	<u>270,364</u>	<u>124,765</u>
Loss from operations	<u>(378,077)</u>	<u>(246,023)</u>	<u>(132,054)</u>
Change in fair value of investments	(25,948)	38,036	(63,984)
Gain on sale of investment	—	—	—
Change in fair value of debt and liability instruments	62,360	23,017	39,343
Gain on deconsolidation of subsidiaries	(12,514)	—	(12,514)
Other income, net	<u>(19,898)</u>	<u>(1,029)</u>	<u>(18,869)</u>
Loss before income taxes	(382,077)	(306,047)	(76,030)
Income tax expense	<u>2,819</u>	<u>38</u>	<u>2,781</u>
Net loss	(384,896)	(306,085)	(78,811)
Net loss attributable to noncontrolling interests	<u>(32,882)</u>	<u>(21,549)</u>	<u>(11,333)</u>
Net loss attributable to Roivant Sciences Ltd.	<u>\$ (352,014)</u>	<u>\$ (284,536)</u>	<u>\$ (67,478)</u>

The following table sets forth our results of operations for the nine months ended December 31, 2022 and 2021:

	Nine Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
Revenue, net	\$ 33,904	\$ 46,063	\$ (12,159)
Operating expenses:			
Cost of revenues	8,953	8,507	446
Research and development	393,358	347,958	45,400
Acquired in-process research and development	97,749	138,377	(40,628)
Selling, general and administrative	474,996	636,060	(161,064)
Total operating expenses	<u>975,056</u>	<u>1,130,902</u>	<u>(155,846)</u>
Loss from operations	<u>(941,152)</u>	<u>(1,084,839)</u>	<u>143,687</u>
Change in fair value of investments	53,277	14,382	38,895
Gain on sale of investment	—	(443,754)	443,754
Change in fair value of debt and liability instruments	90,032	40,747	49,285
Gain on termination of Sumitomo Options	—	(66,472)	66,472
Gain on deconsolidation of subsidiaries	(29,276)	—	(29,276)
Other (income) expense, net	<u>(9,567)</u>	<u>2,529</u>	<u>(12,096)</u>
Loss before income taxes	<u>(1,045,618)</u>	<u>(632,271)</u>	<u>(413,347)</u>
Income tax expense	8,983	532	8,451
Net loss	<u>(1,054,601)</u>	<u>(632,803)</u>	<u>(421,798)</u>
Net loss attributable to noncontrolling interests	(79,188)	(57,603)	(21,585)
Net loss attributable to Roivant Sciences Ltd.	<u>\$ (975,413)</u>	<u>\$ (575,200)</u>	<u>\$ (400,213)</u>

Variance analysis for three and nine months ended December 31, 2022 and 2021

Revenue, net

For the three months ended December 31, 2022 and 2021, our revenue, net consisted of the following:

	Three Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
VTAMA revenues, net	\$ 9,244	\$ —	\$ 9,244
License, milestone, and other revenue	7,808	24,341	(16,533)
Total revenue, net	<u>\$ 17,052</u>	<u>\$ 24,341</u>	<u>\$ (7,289)</u>

Revenue, net decreased by \$7.3 million to \$17.1 million for the three months ended December 31, 2022 compared to \$24.3 million for the three months ended December 31, 2021. During the three months ended December 31, 2022, revenue included \$9.2 million of net product revenues for VTAMA, following the commercial launch in May 2022, with the remaining amount relating primarily to licensing arrangements. During the three months ended December 31, 2021, revenue, net was primarily related to the recognition of milestone income as well as payment for the licensing of technology.

For the nine months ended December 31, 2022 and 2021, our revenue, net consisted of the following:

	Nine Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
VTAMA revenues, net	\$ 14,354	\$ —	\$ 14,354
License, milestone, and other revenue	19,550	46,063	(26,513)
Total revenue, net	<u>\$ 33,904</u>	<u>\$ 46,063</u>	<u>\$ (12,159)</u>

Revenue, net decreased by \$12.2 million to \$33.9 million for the nine months ended December 31, 2022 compared to \$46.1 million for the nine months ended December 31, 2021. During the nine months ended December 31, 2022, revenue included \$14.4 million of net product revenues for VTAMA, following the commercial launch in May 2022, with the remaining amount relating primarily to licensing arrangements. During the nine months ended December 31, 2021, revenue, net was primarily related to payments received in connection with license agreements and the licensing of technology as well as revenue relating to the sales of clinical product and milestone income at Dermavant.

Cost of revenues

For the three months ended December 31, 2022 and 2021, our cost of revenues consisted of the following:

	Three Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
Cost of product and other revenues	\$ 1,358	\$ 1,384	\$ (26)
Amortization of intangible assets	2,228	—	2,228
Cost of revenues	\$ 3,586	\$ 1,384	\$ 2,202

Cost of revenues increased by \$2.2 million to \$3.6 million for the three months ended December 31, 2022 compared to \$1.4 million for the three months ended December 31, 2021. During the three months ended December 31, 2022, cost of revenues included \$0.4 million of costs relating to the sale of VTAMA as well as \$2.2 million of amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022.

For the nine months ended December 31, 2022 and 2021, our cost of revenues consisted of the following:

	Nine Months Ended December 31,		Change
	2022	2021	
		<i>(in thousands)</i>	
Cost of product and other revenues	\$ 3,783	\$ 8,507	\$ (4,724)
Amortization of intangible assets	5,170	—	5,170
Cost of revenues	\$ 8,953	\$ 8,507	\$ 446

Cost of revenues increased by \$0.4 million to \$9.0 million for the nine months ended December 31, 2022 compared to \$8.5 million for the nine months ended December 31, 2021. During the nine months ended December 31, 2022, cost of revenues included \$1.0 million of costs relating to the sale of VTAMA as well as \$5.2 million of amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022. During the nine months ended December 31, 2021, cost of revenues was primarily related to cost associated with the sales of clinical product.

Research and development expenses

For the three months ended December 31, 2022 and 2021, our research and development expenses consisted of the following:

	Three Months Ended December 31,		Change
	2022	2021⁽¹⁾	
	<i>(in thousands)</i>		
<i>Program-specific costs:</i>			
Anti-FcRn franchise ⁽²⁾	\$ 25,181	\$ 12,045	\$ 13,136
Brepocitinib	11,113	13,196	(2,083)
Tapinarof	9,787	14,242	(4,455)
RVT-2001	4,964	120	4,844
Namulumab	3,315	2,228	1,087
AFVT-2101	2,279	3,202	(923)
Other discovery and development programs	21,074	40,672	(19,598)
Total program-specific costs	77,713	85,705	(7,992)
<i>Unallocated internal costs:</i>			
Share-based compensation	6,888	17,669	(10,781)
Personnel-related expenses	31,171	27,050	4,121
Other expenses	9,761	6,921	2,840
Total research and development expenses	\$ 125,533	\$ 137,345	\$ (11,812)

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

(2) Reflects program-specific costs relating to Immunovant's batoclimab program for the treatment of neurology, endocrine, and hematology diseases and Immunovant's IMVT-1402 program.

Research and development expenses decreased by \$11.8 million to \$125.5 million for the three months ended December 31, 2022 compared to \$137.3 million for the three months ended December 31, 2021, primarily due to decreases in share-based compensation of \$10.8 million and program-specific costs of \$8.0 million, partially offset by increases in personnel-related expenses of \$4.1 million and other expenses of \$2.8 million.

The decrease of \$8.0 million in program-specific costs largely reflects the discontinued development of several programs, including ARU-1801, LSVT-1701, DMVT-502, DMVT-503, DMVT-504, and CVT-TCR-01. These decreases were partially offset by increases reflecting the progression of our programs, including Immunovant's anti-FcRn franchise.

For the nine months ended December 31, 2022 and 2021, our research and development expenses consisted of the following:

	Nine Months Ended December 31,		Change
	2022	2021⁽¹⁾ <i>(in thousands)</i>	
<i>Program-specific costs:</i>			
Anti-FcRn franchise ⁽²⁾	\$ 55,278	\$ 32,354	\$ 22,924
Tapinarof	32,770	52,565	(19,795)
Brepocitinib	32,007	13,237	18,770
ARU-1801 ⁽³⁾	12,013	16,882	(4,869)
RVT-2001	11,733	120	11,613
Namulumab	9,424	3,833	5,591
AFVT-2101	8,941	9,306	(365)
LSVT-1701 ⁽³⁾	7,173	9,276	(2,103)
ARU-2801	3,456	9,474	(6,018)
Other discovery and development programs	66,778	59,054	7,724
Total program-specific costs	239,573	206,101	33,472
<i>Unallocated internal costs:</i>			
Share-based compensation	26,548	47,441	(20,893)
Personnel-related expenses	100,886	72,902	27,984
Other expenses	26,351	21,514	4,837
Total research and development expenses	\$ 393,358	\$ 347,958	\$ 45,400

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

(2) Reflects program-specific costs relating to Immunovant's batoclimab program for the treatment of neurology, endocrine, and hematology diseases and Immunovant's IMVT-1402 program.

(3) Reflects a discontinued program.

Research and development expenses increased by \$45.4 million to \$393.4 million for the nine months ended December 31, 2022 compared to \$348.0 million for the nine months ended December 31, 2021, primarily due to increases in program specific costs of \$33.5 million and personnel-related expenses of \$28.0 million, partially offset by a decrease in share-based compensation of \$20.9 million.

The increase of \$33.5 million in program-specific costs largely reflects the progression of our programs and drug discovery, including Immunovant's anti-FcRn franchise, Priovant's brepocitinib program, and Hemavant's RVT-2001 program. The asset acquisition of brepocitinib was completed in September 2021, and the asset acquisition of RVT-2001 was completed in November 2021. Increases in program-specific costs were partially offset by certain decreases, including \$19.8 million for Dermavant's tapinarof program, which was primarily due to a large purchase of clinical product and commercial active pharmaceutical ingredient during the nine months ended December 31, 2021.

Acquired in-process research and development expenses

	Three Months Ended December 31,		Change	Nine Months Ended December 31,		Change
	2022	2021		2022	2021	
		<i>(in thousands)</i>		<i>(in thousands)</i>		
Acquired in-process research and development expenses	\$ 97,749	\$ 16,105	\$ 81,644	\$ 97,749	\$ 138,377	\$ (40,628)

Acquired in-process research and development increased by \$81.6 million to \$97.7 million for the three months ended December 31, 2022 compared to \$16.1 million for the three months ended December 31, 2021, primarily due to consideration for the purchase of IPR&D of \$87.7 million relating to the acquisition of RVT-3101 by a newly-formed subsidiary in November 2022. Additionally, the achievement of a development milestone relating to Immunovant's batoclimab program resulted in a one-time milestone expense of \$10.0 million. Acquired in-process research and development expense for the three months ended December 31, 2021 was primarily driven by consideration for the purchase of IPR&D of \$14.1 million relating to the acquisition of RVT-2001 by Hemavant.

Acquired in-process research and development decreased by \$40.6 million to \$97.7 million for the nine months ended December 31, 2022 compared to \$138.4 million for the nine months ended December 31, 2021. The decrease was primarily due to higher consideration for the purchase of IPR&D during the nine months ended December 31, 2021 as a result of consideration for the purchase of IPR&D of \$82.1 million relating to the acquisition of brepocitinib by Priovant, a one-time milestone expense of C\$50.0 million (approximately \$39 million) due to the achievement of a development milestone related to Dermavant's tapinarof program, and consideration for the purchase of IPR&D of \$14.1 million relating to the acquisition of RVT-2001 by Hemavant. Acquired in-process research and development expenses for the nine months ended December 31, 2022 was driven by consideration for the purchase of IPR&D of \$87.7 million relating to the acquisition of RVT-3101 by a newly-formed subsidiary and the achievement of a development milestone relating to Immunovant's batoclimab program, which resulted in a one-time milestone expense of \$10.0 million.

Selling, general and administrative expenses

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
Selling, general and administrative	\$ 168,261	\$ 115,530	\$ 52,731	\$ 474,996	\$ 636,060	\$ (161,064)

Selling, general and administrative expenses increased by \$52.7 million to \$168.3 million for the three months ended December 31, 2022 compared to \$115.5 million for the three months ended December 31, 2021, primarily due to higher selling, general and administrative expenses at Dermavant as a result of the commercial launch of VTAMA.

Selling, general and administrative expenses decreased by \$161.1 million to \$475.0 million for the nine months ended December 31, 2022 compared to \$636.1 million for the nine months ended December 31, 2021, primarily due to a decrease in share-based compensation expense of \$274.6 million, partially offset by higher selling, general and administrative expenses at Dermavant as a result of the commercial launch of VTAMA. The decrease in share-based compensation resulted from the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination in September 2021, resulting in the recognition of a one-time catch-up expense of \$350.0 million during the nine months ended December 31, 2021 for cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. This decrease was partially offset by continued vesting of the equity instruments.

Change in fair value of investments

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
Change in fair value of investments	\$ (25,948)	\$ 38,036	\$ (63,984)	\$ 53,277	\$ 14,382	\$ 38,895

Change in fair value of investments was an unrealized gain of \$25.9 million and an unrealized loss of \$38.0 million for the three months ended December 31, 2022 and 2021, respectively. The change of \$64.0 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant.

Change in fair value of investments was an unrealized loss of \$53.3 million and an unrealized loss of \$14.4 million for the nine months ended December 31, 2022 and 2021, respectively. The change of \$38.9 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,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
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 \$320 million in cash and a minority equity stake in the combined company.

Change in fair value of debt and liability instruments

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
Change in fair value of debt and liability instruments	\$ 62,360	\$ 23,017	\$ 39,343	\$ 90,032	\$ 40,747	\$ 49,285

Change in fair value of debt and liability instruments were unrealized losses of \$62.4 million and \$23.0 million for the three months ended December 31, 2022 and 2021, respectively. Change in fair value of debt and liability instruments for the three months ended December 31, 2022 primarily consisted of an unrealized loss of \$60.2 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination. 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 were unrealized losses of \$90.0 million and \$40.7 million for the nine months ended December 31, 2022 and 2021, respectively. The change in fair value of debt and liability instruments for the nine months ended December 31, 2022 primarily consisted of unrealized loss of \$55.2 million relating to the NovaQuest facility, which was primarily due to the impact of VTAMA approval in psoriasis, and an unrealized loss of \$40.7 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination. 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.

Gain on termination of Sumitomo Options

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
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 an Asset Purchase Agreement entered into with Sumitomo Pharma Co., Ltd. and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

Gain on deconsolidation of subsidiaries

	Three Months Ended December 31,			Nine Months Ended December 31,		
	2022	2021	Change	2022	2021	Change
	<i>(in thousands)</i>			<i>(in thousands)</i>		
Gain on deconsolidation of subsidiaries	\$ (12,514)	\$ —	\$ (12,514)	\$ (29,276)	\$ —	\$ (29,276)

Gain on deconsolidation of subsidiaries was \$12.5 million for the three months ended December 31, 2022 and resulted from the deconsolidation of a subsidiary in November 2022.

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

Liquidity and Capital Resources

For the nine months ended December 31, 2022 and 2021, we incurred net losses of approximately \$1.1 billion and \$632.8 million, respectively. As of December 31, 2022, we had cash and cash equivalents of approximately \$1.5 billion and our accumulated deficit was approximately \$3.7 billion. Through our subsidiary Dermavant, we launched our first commercial product, VTAMA, following approval by the FDA in May 2022. We began generating product revenue, net from sales of VTAMA in the United States in May 2022. We also have generated revenue through license agreements as well as from subscription and service-based fees. Our revenue through December 31, 2022 has not been significant. 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 October 2022, Immunovant completed an underwritten public offering of 12,500,000 shares of its common stock (including 416,667 shares of common stock purchased by us) at a price to the public of \$6.00 per share, for net proceeds to Immunovant of approximately \$70.2 million after deducting underwriting discounts and commissions and offering expenses.

In October 2022, Myovant Sciences Ltd. ("Myovant") entered into an agreement with Sumitovant Biopharma ("Sumitovant"), its majority shareholder, under which Sumitovant would acquire the remaining shares of Myovant not already owned by Sumitovant at a price of \$27.00 per share in a cash transaction (the "Myovant Transaction"). Under the terms of a Share Return Agreement dated December 27, 2019 between Roivant and Sumitomo Pharma, pursuant to which we retain certain economic rights in respect of 4,243,005 Myovant common shares, in connection with the closing of the Myovant Transaction, we expect to receive approximately \$114.5 million. Sumitovant and Myovant have announced that they expect the Myovant Transaction to close in the quarter ending March 31, 2023, subject to customary closing conditions.

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

In February 2023, we completed an underwritten public offering of 30,666,665 of our common shares (including 3,999,999 common shares issued and sold upon the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$7.50 per share. Total gross proceeds from the offering, including the option exercise, before deducting underwriting discounts and commissions and other offering expenses were \$230 million.

We had cash, cash equivalents and restricted cash of approximately \$1.5 billion at December 31, 2022. Giving effect to our February 2023 follow-on offering for \$230 million in gross proceeds and expected proceeds from the Myovant Transaction of approximately \$115 million, our cash, cash equivalents and restricted cash would have been approximately \$1.9 billion, which we expect to support cash runway into the second half of calendar year 2025. 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.

Our short-term and long-term liquidity requirements as of December 31, 2022 included:

- contractual payments related to our long-term debt (see Note 7, "Long-Term Debt" of our condensed consolidated financial statements);
- obligations under our operating leases;
- certain commitments to Palantir Technologies Inc. ("Palantir") totaling \$30.0 million related to a master subscription agreement entered in May 2021 for access to Palantir's proprietary software for a five-year period;
- certain commitments to Samsung Biologics Co., Ltd. ("Samsung") pursuant to a Product Service Agreement entered between Immunovant and Samsung by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. The minimum purchase commitment related to this agreement is estimated to be approximately \$33.1 million; and
- certain commitments to GSK pursuant to a commercial supply agreement entered between Dermavant and GSK. In conjunction with the purchase agreement of tapinarof between our subsidiary, Dermavant and GSK, Dermavant entered into a clinical supply agreement for which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during our clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and price. The commercial supply agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, Dermavant and GSK amended the terms of the clinical supply and commercial supply agreements which released GSK of certain commitments to supply tapinarof and released Dermavant of certain commitments to purchase tapinarof in exchange for a supplementary fee. Other supply and purchase commitments under the agreements remain in effect. In addition, Dermavant and Thermo Fisher Scientific ("TFS") entered into a Commercial Manufacturing and Supply Agreement for which TFS will provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. The minimum purchase commitment related to these agreements is estimated to be approximately \$34.1 million.

The above purchase commitments do not represent all of our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts. There have been no material changes to the commitments relating to our operating leases during the nine months ended December 31, 2022 outside the ordinary course of business. For further information regarding our lease commitments, refer to Note 12, "Leases" in our Form 10-K.

Additionally, we have certain payment obligations under various asset acquisition and license agreements. Under these agreements we are required to make milestone payments upon successful completion and achievement of certain development, regulatory and commercial milestones. The payment obligations under the asset acquisition and license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones, and we will be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements.

In July 2022, Dermavant paid GSK £100.0 million (approximately \$126 million on the date of achievement) for the regulatory milestone achieved as a result of FDA approval. Additionally, the first sale of VTAMA in May 2022 resulted in the achievement of a milestone to Welicem Biotech Inc. of CAD\$25.0 million (approximately \$20 million on the date of achievement) due within 60 calendar days of the invoice date. Payment for this milestone was made in August 2022.

Following the approval of VTAMA by the FDA in May 2022, Dermavant received \$160.0 million in June 2022 pursuant to the terms of the revenue interest purchase and sale agreement (the "RIPSA") entered with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSA, Dermavant is obligated to pay royalties based on a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States, up to a cap of \$344.0 million, in exchange for the \$160.0 million in committed funding to be paid to Dermavant, conditioned on the approval of tapinarof by the FDA, which was achieved in May 2022. Dermavant used the RIPSA proceeds primarily for the payment of the milestone obligations to GSK and Welicem.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the discovery efforts, preclinical activities, clinical trials and potential commercialization of our product candidates. Additionally, we expect to incur significant commercialization expenses with respect to VTAMA. Our operating results, including our net losses, may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, our expenditures on other research and development activities and our commercialization efforts. We anticipate that our expenses will increase substantially as we:

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

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 proceeds received from 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide.

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, 2022 and 2021:

	Nine Months Ended December 31,	
	2022	2021
	<i>(in thousands)</i>	
Net cash used in operating activities	\$ (664,305)	\$ (530,260)
Net cash (used in) provided by investing activities	\$ (157,822)	\$ 308,997
Net cash provided by financing activities	\$ 289,130	\$ 305,722

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, 2022, cash used in operating activities increased by \$134.0 million to \$664.3 million compared to the nine months ended December 31, 2021. This increase was primarily driven by an increase in cash required to fund operations, particularly as a result of the progression of clinical programs, and to support the commercial launch of VTAMA.

Investing Activities

Cash flow from investing activities includes cash used for milestone payments; purchase of property and equipment; and proceeds from sale of investment.

For the nine months ended December 31, 2022 and 2021, cash flow from investing activities changed by \$466.8 million to net cash used in investing activities of \$157.8 million from net cash provided by investing activities of \$309.0 million for the nine months ended December 31, 2021. This change in cash flow is primarily related to \$320 million in cash we received as a result of the Datavant Merger during the nine months ended December 31, 2021 and milestone payments relating to VTAMA made during the nine months ended December 31, 2022.

Financing Activities

For the nine months ended December 31, 2022, cash provided by financing activities decreased by \$16.6 million to \$289.1 million compared to the nine months ended December 31, 2021. During the nine months ended December 31, 2022, proceeds were generated by funding pursuant to the terms of the RIPSA following the approval of VTAMA by the FDA in May 2022 as well as net proceeds from the issuance of our common shares as well as the common shares of our majority-owned subsidiary Immunovant. 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.

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.

Except as discussed below, there have been no significant 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 for the year ended March 31, 2022 in our Form 10-K.

Product Revenue Reserves

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

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

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, 2022, 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, 2022 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, 2022 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 10—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 not generated significant revenue from our operations since inception, and there is no guarantee that we will do so in the future.

We are a newly commercial-stage biopharmaceutical and healthcare technology company with a limited operating history upon which you can evaluate our business and prospects. We were formed in April 2014, and our operations to date have been limited to acquiring or in-licensing product candidates, efforts to discover new product candidates through our small molecule discovery engine, the creation or acquisition of healthcare technology companies and products, starting or acquiring subsidiary businesses, which we refer to as the Vants, in which to house biopharmaceutical products, product candidates or technologies, and hiring management teams to operate the Vants and oversee the development of our products, product candidates and technologies.

We have recently commenced our transition from a clinical-stage to a company with commercial-stage assets. In May 2022, VTAMA[®] (tapinarof) for the treatment of adults with plaque psoriasis received regulatory approval in the U.S. VTAMA is not currently approved in any other jurisdictions and we do not have any other product candidates that have received regulatory approvals in the U.S. or in any other jurisdiction.

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

- successfully commercialize VTAMA;
- identify new acquisition or in-licensing opportunities;
- successfully complete ongoing preclinical studies and clinical trials and obtain regulatory approvals for our current and future products and product candidates;
- successfully identify new product candidates through our small molecule discovery engine and advance those product candidates into preclinical studies and clinical trials;

- 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, preclinical manufacturing and commercialization efforts and operations;
- launch commercial sales of future 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 products and 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 products and product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of products and product candidates in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

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

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict 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 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 in the U.S. or another jurisdiction, or if there are any delays in any of our or our future collaborators’ clinical trials or the development of our product candidates that we may identify. We anticipate incurring significant costs associated with commercializing VTAMA and any future product candidates, if approved, as well as ongoing compliance efforts.

We may never be able to develop new marketable drugs or successfully commercialize a marketable drug or achieve profitability. To become profitable, we must succeed in developing and commercializing products that generate significant revenue. Revenue from the sale of any products or product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we have or may gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price, the strength and term of patent exclusivity for the product, the competitive landscape of the product market, and whether we own the commercial rights for that territory. For example, even though VTAMA for the treatment of adults with plaque psoriasis has received regulatory approval in the U.S., we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize VTAMA for other indications or in other jurisdictions. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, expand our pipeline, market our products and, if approved, product candidates, and continue our operations. 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 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. While we have received regulatory approval for one product candidate, VTAMA for the treatment of adults with plaque psoriasis in the U.S., we have yet to receive marketing approval for any of our other product candidates anywhere in the world and we have not generated meaningful 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 meaningful product revenue from the commercial sales of our products or, if approved, product candidates or achieve or maintain profitability. It is possible that we will continue to incur substantial operating losses for the foreseeable future. Our ability to generate meaningful product revenue and achieve profitability is dependent on the ability to complete the development of our products and product candidates, obtain necessary regulatory approvals for our current and future products and product candidates and manufacture and successfully market our current and future products and product candidates alone or in collaboration with others.

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

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

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

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

We cannot be certain that additional capital will be available to us or the Vants on acceptable terms, or at all.

If we or the Vants are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our in-licensing and acquisition, discovery, development, commercialization and marketing activities. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our business. Because of the numerous risks and uncertainties associated with our business, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and future product development programs and discovery efforts. Moreover, risks associated with broader market conditions including high levels of inflation and market volatility, both of which have been observed in recent months, may further adversely impact our ability to obtain financing on acceptable terms or at all.

We expect that significant additional capital will be needed in the future to continue our planned operations. 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 at Roivant and the Vants. To the extent that we raise additional capital by issuing equity securities at Roivant or the Vants, our existing shareholders' ownership, or our ownership in the Vants, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of our shareholders. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our products and product candidates, future revenue streams, research programs or technologies or grant licenses on terms that may not be favorable to us. The foregoing restrictions associated with potential sources of additional capital may make it more difficult for us to raise additional capital or to pursue business opportunities, including potential acquisitions.

If adequate funds are not available to us, we may be required to forego potential in-licensing or acquisition opportunities, delay, limit or terminate one or more development or discovery programs, scale back marketing efforts for our current and future products or be unable to expand operations or otherwise capitalize on business opportunities, which could materially affect our business, prospects, financial condition and results of operations.

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

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

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

In addition, in connection with our commercial launch of VTAMA, we expect to continue to increase the amount of cash we spend in order to expand our commercial infrastructure. We expect this level of increased cash spending to increase into this calendar year. The increased level of cash spending will support our transition to an integrated commercial biopharmaceutical company and to support the commercialization of VTAMA. To the extent that we are able to gain regulatory approval for VTAMA in any other jurisdiction besides the U.S. or to gain regulatory approval for any of our other product candidates in any jurisdiction, we would expect to incur additional increased cash costs.

Our limited experience as a commercial-stage company means that there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry, including the risks and uncertainties outlined above. Further, as we continue to develop and seek regulatory approval of additional products and product candidates, as well as additional indications for VTAMA, and to pursue regulatory approvals for VTAMA and other products and product candidates outside the U.S., it could be difficult for us to obtain and devote the resources necessary to successfully manage our commercialization efforts. If we are unable to manage the risks and uncertainties associated with the commercialization of VTAMA and any future products or product candidates that receive marketing approval, we may be unable to generate significant revenues from the sales of these products and product candidates to achieve profitability, which will materially affect our business, prospects, financial condition and results of operations.

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

The success of our business depends in part 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 underserved 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 product candidate on this basis and later determine that the more costly and time intensive trials do not support the initial value the product candidate 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 small molecule discovery engine. As a company we have relatively limited experience in drug discovery generally, with targeted protein degradation and covalency as approaches to target inhibition and with computational discovery as a technology. Our future success depends, in part, on our ability to successfully use these approaches and technologies to identify promising new product candidates and eventually advance those product candidates through preclinical studies and clinical trials.

Only a limited number of product candidates using the approaches of targeted protein degradation or covalency have been approved in the United States, Europe or the United Kingdom. The data underlying the feasibility of developing therapeutic products based on these approaches remains both preliminary and limited. We have not yet succeeded and may not succeed in advancing any product candidates developed using our small molecule discovery engine into clinical trials, demonstrating the efficacy and safety of such product candidates or obtaining regulatory approval thereafter. As a result, it is difficult to predict the time and cost of product candidate development from our small molecule discovery engine and we cannot predict whether the application of these approaches will result in the development and regulatory 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 small molecule discovery engine or computational discovery platforms, would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Because we have limited financial and management resources, we have to make challenging decisions regarding the allocation of capital and personnel across our businesses. We face certain risks associated with these decisions and may fail to capitalize on viable commercial product candidates or profitable market opportunities. For example, we may decide not to pursue a particular in-licensing or acquisition opportunity, or a potential target indication for a product candidate, that later proves to have greater commercial potential than our current and planned development programs and product candidates. Similarly, our management's attention to one product or product candidate may divert their attention from another opportunity that ultimately might have proven more successful. Our spending on current and future research and development programs and other future product candidates may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidate.

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

We face risks associated with the Vant structure.

Our products and product candidates are developed at our Vants, which operate similarly to independent biopharmaceutical companies. 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 sales and marketing, clinical and nonclinical 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 adverse impacts to commercialization or development work at the Vant. These increased expenses, complexities and other challenges may make using and scaling the Vant model more challenging and costly than it would be for a traditional pharmaceutical company to both operate and expand the number of product candidates under development, which could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects. This decentralized model could also make compliance with applicable laws and regulations more challenging to monitor and may expose us to increased costs that could, in turn, harm our business, financial condition, results of operations or prospects.

In addition, a single or limited number of the Vants may, now or in the future, comprise a large proportion of our value. Similarly, a large proportion of our consolidated revenues may be derived from one or a small number of Vants. For example, our only approved product, VTAMA, was developed and is being commercialized by Dermavant, one of our Vants. Any adverse development at Dermavant or any other Vant, including the loss of key members of management, the termination of a key license agreement or other loss of the intellectual property underlying a product or product candidate or the failure of a clinical trial for a product candidate under development at the Vant, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects.

We 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.

The 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 the marketing of our products and our ongoing clinical trials and preclinical 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 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.

We have experienced, and may in the future experience, disruptions as a result of COVID-19 or future pandemics that severely impact our business, commercial and marketing activities, clinical trials and preclinical studies, including:

- our ability to sell and market our current and future products and, if approved, product candidates, including as a result of government-or employer-imposed remote work orders and travel and workplace visitor restrictions;
- a decrease in patient health care utilization due to quarantines, travel restrictions, work from home orders or other public health measures;
- delays or disruptions in our commercial supply chain including as a result of quarantines, travel restrictions, work from home orders or other public health measures;
- 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 nonclinical 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 other 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 preclinical studies, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people and increased reliance on working from home or mass transit disruptions;
- other disruptions to our business generally, including remote working activities 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 resurgence or emergence of new variants of SARS-CoV-2, including variants and sub-variants thereof, 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 market our products and conduct clinical trials and other business activities, and could have a material adverse impact on our operations and financial condition and results. Moreover, the FDA issued a number of guidance documents describing its expectations for how drug manufacturers should comply with various FDA requirements during the pandemic and has otherwise exercised enforcement discretion as to certain requirements due to the ongoing public health emergency. As the pandemic subsides, the determination that a public health emergency exists issued by the U.S. Department of Health and Human Services (“HHS”) Administration for Strategic Preparedness and Response under Section 319 of the Public Health Service Act (“PHSA”) and the determination that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad issued by HHS under Section 564 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) may end, thereby resulting in FDA ceasing such policies and us assuming a greater compliance burden.

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

Our asset in-licensing transactions typically involve low upfront payments 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 the achievement of certain regulatory milestones, including regulatory approval, and then royalty payments upon the achievement of specified levels of sales, which can extend for up to the life of a product. Some of these payments may become due before a product is generating 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 commercialization or development activities or reputational damage. Even for a product that is commercialized and generating revenue, payments could become due that are so large that the investment is not profitable or is less profitable than anticipated. For example, this could occur if at the time of the initial investment, we overestimated the value of the product and agreed to a payment schedule using these inflated estimates. If we are unable to make milestone and royalty payments related to our product candidates when due, our business and prospects could suffer.

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 products and product candidates, assumptions related to adoption of a particular therapy, incidence and prevalence of an indication, use of a product or product candidate versus competitor therapies and size of the addressable patient populations. Some or all of these assumptions may be incorrect. We cannot accurately predict whether our products or product candidates will achieve significant market acceptance in line with these assumptions or whether there will be a market for our products or product candidates that reaches the anticipated size. If any of these assumptions are incorrect or overstated, our results and future prospects will be materially and adversely affected.

We face risks associated with past and future acquisitions, partnerships, alliances or other strategic transactions.

We have historically and may in the future enter into various types of corporate transactions, including acquisitions, strategic partnerships, alliances or collaborations and licensing transactions. These past and future transactions pose certain risks to our business, 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 existing shareholders;
- assimilation of operations, intellectual property and products, including difficulties associated with integrating new personnel;
- diversion of management time and focus away from operating our business;
- the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the counterparty to any such transaction;
- our inability to eventually generate revenue from acquired technology or products or product candidates sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs;
- litigation or other claims, including claims from terminated employees, customers, former shareholders or other third parties.

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 expenses, any of which could have a material adverse effect on our business, prospects, financial condition or results of operations.

Further, any such transactions 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 or other transaction 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 products or product candidates 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 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.

Our business may suffer reputational harm due to our inability to successfully commercialize VTAMA or other failures of our product candidates, which could have further adverse impacts on our business.

Our inability to successfully commercialize VTAMA or the failure of any of our product candidates in ongoing or future clinical trials or preclinical studies, in addition to having a direct adverse impact on our business and prospects, could also have a lasting negative impact on our reputation, which could, in turn, impact our ability to successfully enter into future licensing arrangements or other transactions with potential counterparties, raise future capital or attract key personnel to join us. As a result, our business and prospects would be materially harmed and our results of operations and financial condition would likely suffer materially.

Risks Related to the Development of Our Products and Product Candidates

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

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

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

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

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

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

- failure to obtain regulatory authorization to commence a clinical trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies;
- other regulatory issues, including the receipt of any inspectional observations on FDA’s Form-483, Warning or Untitled Letters, clinical holds, or complete response letters or similar communications/objections by other regulatory authorities;
- unforeseen safety issues, or subjects experiencing severe or unexpected adverse events;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- resolving any dosing issues, including those raised by the FDA or other regulatory authorities;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other regulatory authorities;

- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- an IRB or EC refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- premature discontinuation of study participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of our product candidates or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

In addition, disruptions caused by the COVID-19 pandemic may 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, or the principal investigator, are failing to conduct a trial in accordance with the protocol, applicable regulatory requirements, including Good Clinical Practice (“GCP”) regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority finds deficiencies in our IND or equivalent applications for other countries or in the manner in which clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials.

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

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

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

Our approach to the discovery and development of product candidates from our small molecule discovery engine 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, covalency and similar approaches is novel and unproven. Our future success depends in part on the successful development of these new therapeutic approaches. Very few small molecule product candidates using targeted protein degradation or covalency have been tested in humans. Only a limited number of product candidates using targeted protein degradation or covalency have been approved in the United States, Europe or the United Kingdom and the data underlying the feasibility of developing these types of therapeutic products remains both preliminary and limited. If any adverse learnings are made by other developers of protein degraders or covalent inhibitors, 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 product candidates from our small molecule discovery engine 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 these product 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 small molecule discovery engine 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 products or product candidates that we cannot predict at this time.

Additionally, the regulatory approval process for novel product candidates such as those associated with our small molecule discovery engine 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 and similar approaches, only a limited number of product candidates of this type have been approved in the United States, Europe or the United Kingdom. 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 our product candidates will receive marketing approval or achieve commercial acceptance. Any development problems we experience in the future related to our small molecule discovery engine 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 preclinical 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 products and product candidates are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

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

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

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

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

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

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

Patient enrollment and retention in clinical trials depends on many factors, including EC approval of patient participation as proposed, the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors, 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 and our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our products and 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 products or product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. 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 current and 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 products and product candidates, or could render further development impracticable. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Any such delays in our current or future clinical trials could have a material adverse impact on our operations and financial condition and results.

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

Success in preclinical 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 preclinical studies and earlier clinical trials. For example, we cannot assure you that the reductions in IgG antibodies that we have observed to date in our clinical trials and preclinical studies of batoclimab and IMVT-1402 and will be observed in any future clinical trials. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unobserved adverse events.

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

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

From time to time, and in some countries, in line with the applicable requirements set out in legislation and guidance, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data. For example, we recently disclosed interim data from the induction portion of the TUSCANY-2 trial of RVT-3101 in ulcerative colitis. These results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously reported. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares.

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

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

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

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

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

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

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

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

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

We do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Accordingly, we rely on third parties to produce commercial and clinical supplies of our products and product candidates. For example, Dermavant and GSK have entered into manufacturing and supply agreements pursuant to which GSK is providing both commercial drug product and drug substance for VTAMA as well as drug product and drug substance for Dermavant’s ongoing Phase III clinical trial of VTAMA in atopic dermatitis. If GSK does not fulfill its obligations under these agreements, Dermavant’s ability to sell VTAMA commercially and conduct its ongoing and future clinical trials with VTAMA may be adversely impacted.

Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our products or product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our products for commercialization and products or product candidates for our preclinical studies, clinical trials and research and development activities. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, or of equipment and devices as necessary, for either commercialization or an ongoing clinical trial, due to the need to replace a third-party manufacturer or otherwise, could considerably delay marketing efforts for the product in question or the completion of clinical trials, product testing and potential regulatory approval of the product candidate in question. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our products or product candidates, the commercial launch of our products or product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products or product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our products or product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involve committing substantial financial resources to current or future products or product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals were recently enacted or are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the 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 products and product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or other similar application to the FDA. Such facilities must also register with the FDA. Similar requirements apply in other jurisdictions. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with Current Good Manufacturing Practice (“cGMP”) requirements for the manufacture of products and product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable non-U.S. regulatory authorities, we will not be able to secure or maintain regulatory approval for our products or product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable non-U.S. regulatory authorities do not approve these facilities for the manufacture of our products or product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products and develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Approval and Commercialization of Our Products and Product Candidates

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

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

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

- we may not be able to demonstrate that a product candidate is safe and effective as a treatment for the targeted indications, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure and potent for use in its targeted indication, to the satisfaction of the FDA or other relevant regulatory authorities;
- the FDA or other relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase costs and prolong development timelines;
- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of clinical trials, including the design of proposed preclinical and early clinical trials of any future product candidates;

- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact the clinical trials and ability to obtain marketing approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical, preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, preclinical studies or clinical trials or may require additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites, including in situations where the authorities deem that the data was not generated in compliance with GCP, ethical standards or applicable data protection laws;
- if an NDA, BLA or a similar application is 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 authorities, as the case may be, require, as a condition of approval, additional nonclinical, preclinical 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 candidates;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA’s concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders, the FDA’s goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval. The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates.

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

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

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

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

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

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

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

Adverse events caused by or associated with our products and product candidates have caused us and could, in the future, cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidates or those from other companies targeting similar diseases, could also affect patient recruitment or the ability of enrolled patients to complete their participation in our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. For example, as previously disclosed, our subsidiary Immunovant voluntarily paused dosing in early phase clinical studies for batoclimab globally to evaluate batoclimab-induced elevations in total cholesterol and LDL levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory agencies, Immunovant is continuing its clinical development of batoclimab. While Immunovant does not expect that increases in LDL over a short-term treatment duration would pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. These occurrences have harmed, and any reoccurrence may continue to harm our business, financial condition and prospects.

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

- regulatory authorities may withdraw, 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 distribution, marketing or manufacturing processes of the products or any components thereof, including a “black box” warning or contraindication on product labels or communications containing warnings or other safety information about the product;
- regulatory authorities may require the addition of 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 distributed, conduct additional clinical trials, change the labeling of a product or conduct additional post-marketing studies or surveillance;
- we may be required to repeat preclinical studies or clinical trials or terminate programs for a product candidate, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we may be sued and held liable for harm caused to patients, or may be subject to fines, restitution or disgorgement of profits or revenues;
- physicians may stop prescribing a product;
- reimbursement may not be available for a product;
- we may elect to discontinue the sale of our products;
- our products may become less competitive; and
- our reputation may suffer.

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

The regulatory approval processes of the FDA and comparable non-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable, and gaining approval for a product candidate in one country or jurisdiction does not guarantee that we will be able to obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

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

FDA approval for a product candidate in the United States does not guarantee that we will be able to or that we will make efforts to obtain approval for or commercialize our product candidates in any other jurisdiction, which would limit our ability to realize the drug candidate's full market potential.

We have one product, VTAMA, approved by the FDA for the treatment of plaque psoriasis in adults in the U.S. In order to market VTAMA or any of our other products or product candidates 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 preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the 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 process outside of the United States may include all of the risks associated with obtaining FDA approval. Other than VTAMA, we do not have any products or product candidates approved for sale in any jurisdiction, including international markets, and we do not have significant experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

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

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

The FDA and other relevant regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs, result in regulatory enforcement, or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved 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 products or product candidates for their approved indications or in a manner which regulators believe to be truthful and non-misleading, we may be subject to enforcement action. Moreover, in the EU and the UK we will be prohibited from promoting prescription-only medicinal products to individuals who are not healthcare professionals. Violations of the FDCA in the United States and other comparable laws and regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non-U.S. regulatory agencies alleging violations of 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 products or product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may negatively impact our business and the price of our Common Shares and may yield various results, including:

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

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

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

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

- monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good applicable practice ("GxP") (e.g., GCP, GLP and GMP regulated) products;

- monitoring and providing oversight of all GxP suppliers (e.g., contract development manufacturing organizations and CROs);
- establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and
- cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality.

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

Breakthrough Therapy Designation, Fast Track Designation, 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.

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

Recently, there has been heightened scrutiny of the accelerated approval pathway, with some stakeholders advocating for reform. The HHS Office of Inspector General has initiated, and partly completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Consolidated Appropriations Act, 2023, revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things, requires the FDA to specify the conditions for required post-marketing trials, permits the FDA to require such trials to be underway prior to, or within a specific period after, approval, requires sponsors to provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed, makes the failure to conduct required post-marketing trials with due diligence and the failure to submit the required reports prohibited acts, and details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis. At this time, it is not clear what impact, if any, these developments may have on the statutory accelerated approval pathway or our business, financial condition results of operations, or prospects.

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

Regulatory authorities in some jurisdictions, including the 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 of marketing exclusivity 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 grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, Orphan Drug Designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to certain benefits, such as scientific assistance (protocol assistance), financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission, EMA and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the "normal" data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company's preclinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic 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.

The above incentives and exclusivities regime in the EU are a particular focus of an upcoming reform of the EU pharmaceutical legislation. As a result, in the future, these incentives and exclusivities may be restricted or made conditional upon compliance with additional regulatory obligations. The related new legislative proposal by the European Commission is currently expected in March 2023.

If we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the European Commission can subsequently approve the same drug for a different condition or the same condition if the FDA or the EMA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EEA, a marketing authorization may also be granted, for the same therapeutic indication, to a competitor with a similar medicinal product during the exclusivity period if we are unable to supply sufficient quantities of the medicinal product for which we received marketing authorization. Moreover, our orphan exclusivity may be reduced if we are unable to comply with any new obligation that may be imposed by the upcoming reform of the EU pharmaceutical legislation, as discussed above.

Moreover, a September 2021 Eleventh Circuit decision in *Catalyst Pharmaceuticals, Inc. vs. Becerra* regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug's orphan designation could significantly broaden the scope of orphan drug exclusivity for such products. In January 2023, the FDA, however, issued a Federal Register notice clarifying its approach to orphan drug exclusivity following the *Catalyst* decision that suggests this may not be the agency's intended direction going forward. Consistent with the court's decision, the FDA set aside its approval of the drug at issue in the case. The notification announced that, while complying with the court's order in *Catalyst*, the FDA intended to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order. Legislation has also been introduced that may reverse the *Catalyst* decision.

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

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

- the efficacy and safety of such products and product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments, including any similar generic treatments;
- the ability to offer these products for sale at competitive prices;
- the ability to offer appropriate patient financial assistance programs, such as commercial insurance co-pay assistance;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product or product candidate is approved by FDA or comparable non-U.S. regulatory agencies;
- product 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 adverse events.

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the “Affordable Care Act” or “ACA”), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”), which created an abbreviated approval pathway under section 351(k) of the PHSA for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, a section 351(k) application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product submitted under section 351(a) of the PHSA containing the competing sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company’s product. The law is complex and is still being interpreted and implemented by the FDA and the FDA only approved the first interchangeable biosimilar in July 2021. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples legislation, purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, including by allowing generic drug, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biological product samples. Its provisions do have the potential to facilitate the development and future approval of biosimilar versions of our products, introducing biosimilar competition that could have a material adverse impact on our business, financial condition and results of operations.

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

If we are unable to continue to expand our sales, marketing and distribution capabilities or enter into agreements with third parties to sell, market and distribute our products and product candidates, we may not be successful in commercializing those products and, if approved, product candidates.

We are currently in the process of establishing an infrastructure for the sales, marketing and distribution of VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U.S. The costs of establishing and maintaining this infrastructure may exceed the cost-effectiveness of doing so. In order to effectively market our products and, if approved, product candidates, we must continue to expand 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 our products and, if approved, product candidates, we will need an effective sales and marketing organization or to outsource these functions to third parties. To the extent we seek to do so, there is no guarantee that we will be able to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to our products or product candidates.

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 or, if approved, product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.

Factors that may inhibit our efforts to commercialize a product or, if approved, product candidate on our own include:

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

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of a product or, if approved, product candidate, we may be forced to delay commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we 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 a product or, if approved, product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to our products or product candidate or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

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

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

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

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program (such as Medicare and Medicaid). The term “remuneration” has been broadly interpreted by the federal government to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain activities from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to \$100,000 for each violation. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal false claims laws, including the False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim; or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties currently ranging from \$11,803 to \$23,607 for each false claim or statement for penalties assessed after December 13, 2021, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses and most healthcare providers (collectively, “covered entities”), and such covered entities’ “business associates,” defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of the covered entity;
- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personally identifiable data, including personal health information;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value” to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and EU and foreign national laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and several recently passed state laws that require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes, some of which contain ambiguous requirements that government officials have not yet clarified; and EU and foreign national laws prohibiting promotion of prescription-only medicinal products to individuals other than healthcare professionals, governing strictly all aspects of interactions with healthcare professionals and healthcare organizations, including prior notification, review and/or approval of agreements with healthcare professionals, and requiring public disclosure of transfers of value made to a broad range of stakeholders, including healthcare professionals, healthcare organizations, medical students, physicians associations, patient organizations and editors of specialized press.

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

Healthcare legislative 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 restrict or regulate post-approval activities for our products and affect our ability to profitably sell our products, and prevent or delay marketing approval of our current and any future product candidates. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product 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, subjected biological products to potential competition by lower-cost biosimilars, addressed 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, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a 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. However, effective January 1, 2025, this program will be eliminated as a part of the Part D benefit redesign enacted under the Inflation Reduction Act, discussed below.

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. During previous Congressional sessions, Congress had introduced several pieces of legislation aimed at significantly revising or repealing the ACA and may in the future consider legislation to replace, modify or augment elements of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through the first six months of 2023 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. There was a 1% reduction through the end of June 2022, after which the cuts returned to 2%. Absent further Congressional action, there is a possibility that an up to 4% Medicare sequester could be triggered in January 2023, pursuant to the Statutory Pay-As-You-Go Act of 2010 ("PAYGO"). Under PAYGO, if the five- or ten-year PAYGO scorecard shows a net cost at the end of a Congressional session, then the Office of Management and Budget is required to issue a sequestration order. The American Rescue Plan Act of 2021 was expected to trigger a PAYGO sequestration order at the end of the 2021 Congressional session. However, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024.

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. 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. Moreover, in August 2022, Congress enacted the Inflation Reduction Act ("IRA"), a law with sweeping changes to the payment of drugs under the Medicare program. Among other provisions, the IRA contains (i) a drug price negotiation program for certain high spend Medicare drugs that have been on the market for a certain length of time and lack generic or biosimilar competition under which Medicare prices for such drugs are capped by a "maximum fair price"; (ii) new manufacturer rebate obligations on certain drugs paid under Medicare Part B or D whose prices increase faster than inflation relative to a benchmark period; and (iii) a redesign of the Part D benefit, including capping patients' annual out-of-pocket costs on Part D drugs, lowering the beneficiary out-of-pocket threshold, streamlining the Part D benefit to eliminate the "coverage gap" phase, and replacing the manufacturer coverage gap discount program with a new manufacturer discount program that provides discounts throughout the post-deductible benefit phases. It is possible that Congress or the Administration may take further actions to control drug prices. In October 14, 2022, President Biden issued an executive order calling on the Secretary to consider whether to select for testing by the CMS innovation center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. We cannot predict how these new provisions would be implemented or their impact on Roivant.

Additionally, U.S. regulators continue to pursue policies designed to lower drug costs for federal programs and patients. In May 2019, the Centers for Medicare and Medicaid Services (“CMS”), issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. This rulemaking also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. However, Congress has adopted various delays on the implementation or enforcement of the rule, including a postponement until January 2032 under the IRA. On December 31, 2020, CMS enacted a final rule expanding the scope of drug products that may be considered “line extensions” subject to inflationary rebates under the Medicaid Drug Rebate Program.

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

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

- the demand for our products and, if approved, product candidates;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve 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 our products and, if approved, product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or successfully commercialize our products and, if approved, product candidates.

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

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

In the United States, no uniform policy of coverage and reimbursement exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product or, if approved, product candidate will be made on a plan-by-plan basis. 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 or, if approved, product candidates, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product or product candidate. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products or, if approved, product candidates, to the extent that patients who are prescribed our products or, if approved, product candidates, are not separately reimbursed for the cost of the product.

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

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

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

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

We may face competition in the United States for our products and, if approved, product candidates, 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 our products and, if approved, product candidates. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for our products and, if approved, product candidates and adversely affect our future revenues and prospects for profitability.

Other Risks Related to Our Business and Industry

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

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

Our senior leaders and key employees may terminate their positions with us at any time. Due to the small number of employees at some of the Vants, the loss of a key employee may have a larger impact on our business. In particular, we rely on a limited number of employees in certain key jurisdictions, including the 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 highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

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

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

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

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

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our products or, if approved, product candidates, in various countries;
- difficulties in managing operations in different jurisdictions;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to currency exchange rate fluctuations;

- varying protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the 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 commercializing our products and, if approved, 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 products and, if approved, 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 certain regulatory approvals before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize our products and, if approved, product candidates and ultimately harm our financial condition.

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

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development and commercialization of products and product candidates for the treatment of the indications that we are also pursuing. Examples of such competing products include, but are not limited to:

- ZORYVE (roflumilast), a topical PDE4 inhibitor, a potential competitor to VTAMA;
- OPZELURA (ruxolitinib), a topical Janus kinase inhibitor, a potential competitor to VTAMA;
- PRA023, an TL1A antibody, a potential competitor to RVT 3101;

- VYVGART (efgartigimod alfa-fcab), a neonatal Fc receptor blocker, a potential competitor to batoclimab and IMVT-1402;
- Nipocalimab and rozanolixizumab, anti-FcRn antibodies, potential competitors to batoclimab and IMVT-1402;
- TEPEZZA (teprotumumab-trbw), an insulin-like growth factor-1 receptor inhibitor, a potential competitor to batoclimab; and
- SOTYKTU (deucravacitinib), a TYK2 inhibitor, a potential competitor to brepocitinib.

If any of these or other competitors, including competitors for our other product candidates, receive FDA approval before we do, our products or product candidates would not be the first treatment on the market, and our market share may be limited.

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

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

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

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

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

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

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

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

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

We may not hold a controlling stake in certain of our 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 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 protections.

Our computer systems, as well as those of various third parties on which we presently rely, or may rely on in the future, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from or otherwise be subject to computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, and/or other third parties. Any of the foregoing may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risks of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-state and nation-state-supported actors, sovereign governments and cyber terrorists, have generally increased over time, including for geopolitical reasons and in conjunction with military conflicts and defense activities, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our products and product candidates. In addition, there may be an increased risk of cybersecurity attacks due to the onset of hostilities by Russia towards Ukraine, including cybersecurity attacks perpetrated by Russia or others at its direction in response to economic sanctions and other actions taken against Russia as a result of its invasion of Ukraine. Any increase in such attacks on us or our third-party vendors or other systems could adversely affect our network systems or other operations.

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

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

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

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. Failure to comply with applicable privacy and data security laws and regulations could result in enforcement actions against us, including possible fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

In addition, many U.S. states in which we operate have laws that protect the privacy and security of personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act (the “CMIA”), a statute similar to the HIPAA privacy and security regulations, expressly applies to pharmaceutical companies (as well as companies that provide certain technologies for processing personal health information), and imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA, with limited exceptions, requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information and requires pharmaceutical companies to maintain reasonable security measures to protect such information. The CMIA authorizes administrative fines and civil penalties of up to \$25,000 for willful violations and up to \$250,000 if the violation is for purposes of financial gain, as well as criminal fines. In addition, another more broadly applicable California law, the California Consumer Privacy Act of 2018 (the “CCPA”), which as substantially amended in 2020 pursuant to the California Privacy Rights Act (the “CPRA”) generally requires us to provide notice to California residents regarding the personal information we collect, use and share and to honor such residents’ privacy rights, including the right to opt-out of the sale of their 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. Both the California Attorney General and an agency established pursuant to the CPRA amendments, the California Privacy Protection Agency, have authority to implement and enforce the CCPA. California’s aggressive steps to protect consumer privacy have been followed by similar actions in other states, including Virginia, Colorado, Utah and Connecticut, all of which have enacted CCPA/CPRA-like laws 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 this growing body of privacy and data protection laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Outside of the 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. The EU-US Privacy Shield was such a transfer mechanism put in place by the EU and the United States, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union (“CJEU”). A replacement of the Privacy Shield is currently being developed. On December 13, 2022, following the signature of a U.S. Executive Order by President Biden on October 7, 2022, the European Commission issued a draft adequacy decision which, if adopted and not successfully challenged in court, is intended to address the concerns expressed by CJEU in their 2016 ruling and allow transfer of personal data from the EEA to companies in the U.S. which commit to comply with the EU-U.S. Data Privacy Framework. At the moment it is unclear if the adequacy decision will be adopted at EU level and whether the anticipated legal challenges against this decision, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful.

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. Due to potential legal challenges, it remains to be seen whether SCCs will remain a valid legal mechanism and whether additional means for lawful data transfers will become available. In June 2021, the European Commission adopted new SCCs that are designed to be a mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, the SCCs are a valid mechanism to transfer personal information outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. The new SCCs may increase the legal risks and liabilities under European privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs, any transfers by us or our vendors of personal information from Europe may not comply with European data protection law, which may increase our exposure to the GDPR’s heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of E.U. personal information outside of the E.U. (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products. 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 the 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 laws and regulations being adopted and coming into effect. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. Significant resources are needed to understand and comply with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties 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 absent any findings that we have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

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

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

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

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our products and, if approved, product candidates.

The sale of our products, including VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U.S. and the use of our existing product candidates in clinical trials expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products or product candidates. On occasion, large judgments have been awarded in class action lawsuits where drugs have had unanticipated harmful effects. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- delays in or an inability to commercialize VTAMA, and any future products for which we obtain marketing approval;
- impairment of our business reputation and significant negative media attention;
- delay or termination of clinical trials, or withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products, 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. We have acquired insurance coverage which extends to liabilities arising from the sale of our products; however, there is no assurance that we will be able to maintain this insurance coverage on commercially reasonable terms or in adequate amounts or that this coverage will be sufficient to cover any losses arising from any claims related to our products or, if approved, product candidates. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business, including preventing or limiting the commercialization of our products and, if approved, product candidates.

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

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

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

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

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

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

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

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

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

We are centrally managed and controlled 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. A trade and cooperation agreement which outlines the trading relationship between the U.K. and E.U. now that the transition period has concluded, applied provisionally from January 1, 2021 and formally entered into force on May 1, 2021.

There continues to be 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 further 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. The EU Clinical Trials Regulations which govern the conduct of clinical trials in the E.U. entered into application in January 2022 and consequently do not apply in the U.K. 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 products and, if approved, 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. There are also differences between the regulatory regimes. For example, 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 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. Further, there is no designation step required in the UK, and the criteria for orphan designation will be determined at the time of authorization.

Given these uncertainties, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or EEA for our products and 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 or Great Britain 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 products and 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 products or 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 products and 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, products and product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

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

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of their research and development output, such as employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, while we have pre-publication review procedures in effect, premature or inadvertent publication of potentially patentable subject matter could preclude our ability to obtain patent protection. We may choose not to seek patent protection for certain innovations, products or product candidates and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, our products and, if approved, product candidates may not be protected by patents in all jurisdictions. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and product candidates and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and, if approved, product candidates and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. The patent applications that we own or in-license may fail to result in issued patents with claims that cover products or product candidates in the 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 current and future products or product candidates 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 or product candidate that is ultimately commercialized. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may ultimately obtain. Even if patents do successfully issue and even if such patents cover our current and future products and product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowly construed, invalidated, or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or product candidates or limit the length of terms of patent protection we may have for our products, product candidates and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing products or product candidates, or practicing our own patented technology, or impose a substantial royalty burden to do so. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products or, if approved, product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products or, if approved, product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our products, product candidates or other technologies, competitors and other third parties could market products or product candidates and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The standards that the U.S. Patent and Trademark Office (the “USPTO”) and its counterparts in other countries use to grant patents are not always applied predictably or uniformly. In addition, the laws of countries other than the 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, products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. Changes in either the patent laws or interpretation of the patent laws in the 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 licensed 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. Briefing is complete and oral arguments before the Federal Circuit took place in November 2022. Additionally, one European patent (EU patent no. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licensed from Arbutus is the subject of an opposition proceeding brought 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, products or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or commercialize products and, if approved, product candidates without infringing third-party patent rights or result in our breach of agreements pursuant to which we license such rights to our collaborators or licensees. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products and product candidates, or limit the duration of the patent protection of our technology, products and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third-party may develop a competitive product that provides benefits similar to one or more of our products or product candidates but that falls outside the scope of our patent protection. Moreover, patents have a limited lifespan. In the 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 products and product candidates, it may be open to competition from generic versions of such products or product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our own and, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. In the 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 or product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, are limited. Even if patents covering products or product candidates are obtained, once the patent life has expired, we may be open to competition from other products or product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new products and product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, the patent covering the use of VTAMA as an active ingredient to treat psoriasis and atopic dermatitis, but not limited to any formulation, expired in December 2020. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our products and product candidates.

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

Composition-of-matter patents on the active pharmaceutical ingredient (“API”) in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. While we generally seek composition of matter patents for our products and product candidates, such patents may not be available for all of our products and product candidates. For example, we do not own or have a license to any issued composition of matter patents in the United States or any other jurisdiction with respect to VTAMA. Instead, we rely on an issued U.S. patent claiming topical formulations of VTAMA, including the formulation studied in Phase 3 trials and approved by the FDA, 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 products and product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products and, if approved, product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

In addition, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that it licenses from third parties. Therefore, we cannot be certain that these or other patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. Additionally, we may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. If our current or future licensors or collaboration partners fail to obtain, maintain, defend, protect or enforce any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize products and product candidates that are the subject of such licensed rights could be adversely affected.

Furthermore, certain of our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology, products and product candidates in the future. The intellectual property portfolio licensed to us by our licensors at least in some respects, may therefore be used by such licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. For example, Immunovant does not have rights to develop, manufacture, use or commercialize batoclimab or 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 VTAMA in China, including Hong Kong, Macau or Taiwan, as such rights were retained by Welichem Biotech Inc. or licensed to third parties. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

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

Our commercial success depends in part on our avoidance of infringement, misappropriation and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Our competitors or other third parties may assert infringement claims against us, alleging that our products or product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. There is a substantial amount of litigation, both within and outside the 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 products, product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products or product candidates. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents.

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

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

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

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

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

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of products or product candidates in any jurisdiction. Patent applications in the 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 products and product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current and future products and product candidates, or the use thereof, provided such pending patent applications result in issued patents. Our ability to develop and market our current and future products and product candidate can be adversely affected in jurisdictions where such patents are issued.

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

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

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

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time-consuming, even if ultimately successful. For example, in February 2022, Roivant's subsidiary, Genevant Sciences, and Arbutus Biopharma Corporation filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna, Inc. and an affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19 (the "Moderna Action"). In addition, in March 2022, Acuitas Therapeutics Inc. filed a lawsuit in the United States District Court for the Southern District of New York against Genevant Sciences and Arbutus Biopharma Corporation seeking a declaratory judgment that U.S. Patents 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127, 9,504,651, 9,518,272, and 11,141,378 are not infringed by the manufacture, use, offer for sale, sale or importation into the United States of COMIRNATY, Pfizer's and BioNTech's vaccine for COVID-19 and are otherwise invalid (the "Acuitas Action").

In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court and if any such suits, including the Moderna Action and the Acuitas Action, will ultimately be resolved successfully. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives, or could put our patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the 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 products or product candidates. Such a loss of patent protection could harm our business. Additionally, any adverse outcome could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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

Many patents that we own or have licensed are assigned to or licensed by our direct or indirect subsidiaries. For example, any patents that Immunovant has licensed are assigned to its wholly-owned subsidiary Immunovant Sciences GmbH and any patents that Dermavant owns or has licensed are assigned to its wholly-owned subsidiary Dermavant Sciences GmbH. If a third-party is found to be infringing such patents, we and our direct subsidiaries may not be able to permanently enjoin the third-party from making, using, offering for sale or selling the infringing product or activity for the remaining life of such patent in the 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 products and product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the 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 has 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 acquired or in-licensed patent rights and technology for certain products or product candidates was funded in part by the U.S. federal government. As a result, the federal government may have certain rights to such patent rights and technology, which include march-in rights. If the federal government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The federal government's rights may also permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The federal government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. Further, the recipient of U.S. government funding is required to comply with certain other requirements, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. The U.S. government has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, our rights in such inventions may be subject to certain requirements to manufacture products or product candidates embodying such inventions in the 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 products or product candidates, or patents that cover our biologic product candidates, can be challenged by third parties.

If a third-party files an application under Section 505(b)(2) or an abbreviated new drug application (“ANDA”) under Section 505(j) with respect to any of our products or, if approved, product candidates, for a generic product containing any of our products or product candidates, including VTAMA (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 product or, if approved, product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party’s generic product. A certification under 21 CFR § 314.94(a)(12)(i)(A)(4) that the new product will not infringe the Orange Book-listed patents for the applicable product or, if approved, product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third-party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party’s ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party’s ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third-party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party’s ANDA will not be subject to the 30-month stay of FDA approval.

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

For example, our three issued U.S. patents covering VTAMA may not provide adequate protection from competitive products developed by 505(b)(1) NDA, 505(b)(2) NDA or 505(j) ANDA applicants containing paragraph IV certifications if such applicants are able to design around the 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 VTAMA 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 VTAMA 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 our products and product candidates.

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

Filing, prosecuting and defending patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the 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 products and product candidates and may also export infringing products and product candidates to territories where we have patent protection, but enforcement is not as strong as that in the United States. These product candidates may compete with our products or product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the 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, products and product candidates and could result in our inability to develop, manufacture or commercialize our products and product candidates without infringing third-party patent rights. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our current or future products and product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may harm our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would harm our business, results of operations and financial condition.

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

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

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

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

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

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

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

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

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

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

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

We rely on trademarks as one means to distinguish our products from the products and product candidates of our competitors. Our current and future trademark applications in the 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 products or product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, *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 our products or product candidates, but that are not covered by the claims of the patents that we own;

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

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

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

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

If our performance does not meet market expectations, the price of our Common Shares may decline. In addition, 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;
- receipt of marketing approval for a product or product candidate in one or more jurisdictions, or the failure to receive such marketing approval;
- the results of clinical trials or preclinical studies conducted by us and the Vants;
- changes in financial estimates and recommendations by securities analysts concerning us, the Vants or the biopharmaceutical industry and market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- changes in laws and regulations affecting our and the Vants’ businesses;
- the outcome of litigation or other claims or proceedings, including governmental and regulatory proceedings, against us or the Vants;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- the volume of our Common Shares available for public sale and the relatively limited free float of our Common Shares;
- any significant change in our board of directors or management;
- sales of substantial amounts of our Common Shares by directors, executive officers or significant shareholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

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

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act.

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

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 has 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 securities, including convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Common Shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. In addition, new investors could gain rights superior to our existing shareholders.

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

Issuance of options 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 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. Certain of these shareholders remain subject to lock-up arrangements in respect of a portion of their Common Shares and as a result there may be limited liquidity in the trading market for our Common Shares during the period in which these lock-up agreements are in effect. 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, including as a result of the denial of treaty benefits that we may claim. Any such additional tax liability could materially adversely affect our results of operations.

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

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

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

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

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

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

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock-based compensation; (6) changes in tax laws (including tax treaties) or the interpretation of such tax laws (including tax treaties) and changes in U.S. generally accepted accounting principles; 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 thereof. Accordingly, under generally applicable U.S. federal income tax rules, since we were not created or organized in the United States or under the law of the United States or of any state thereof but are instead a Bermuda incorporated entity and tax resident of the U.K., we would generally be classified as a non-U.S. corporation. Section 7874 of the Internal Revenue Code of 1986, as amended (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 “United States persons as defined in the Code (“U.S. holders”) 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 application of Section 7874 of the Code is complex and is subject to detailed Treasury regulations that could be impacted by changes in such Treasury regulations with possible retroactive effect, and the interpretation of Treasury regulations relating to the required ownership of us is subject to uncertainty for which 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, our non-U.S. subsidiaries will 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, if we own (directly or indirectly) at least 25% (by value) of the stock of another corporation, for purposes of determining whether we are a PFIC, generally we would be treated as if we held our proportionate share of the assets of such other corporation and received directly our proportionate share of the income of such other corporation (the “Look-Through Rule”) and generally we would retain the character of such assets and income as if they were held directly by us rather than by such other corporation (but see below for the discussion on an exception to the Look-Through Rule). If we are characterized as a PFIC, U.S. holders of our Common Shares may suffer adverse tax consequences, including having gains realized on the sale of our Common Shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our Common Shares by individuals who are U.S. holders, and having interest charges apply to certain distributions by us and the proceeds of sales or other dispositions of our Common Shares that result in a gain to the U.S. holder. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset. If we are a CFC (determined by disregarding certain downward attribution rules) and not publicly traded for the relevant taxable year, however, the test shall be applied based on the adjusted basis of our assets. Because our Common Shares should be considered to be “publicly traded” for the taxable years ending on March 31, 2022 and March 31, 2023, we would apply the 50% passive asset test using the fair market value of our assets. In addition, our status may also depend, in part, on how quickly we utilize our cash on-hand and cash from future financings in our business.

Treasury regulations adopted in 2021 (the “2021 Regulations”) modify certain of the rules described above. The 2021 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 2021 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 2021 Regulations.

Based on the foregoing, with respect to the taxable year that ended on March 31, 2022, 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, 2022 and based upon the fair market value of our assets, including any goodwill and intangible property, and the nature and composition of our income and assets.

Our status as a PFIC is a fact-intensive determination made on an annual basis, which is subject to uncertainties, including but not limited to the fact that the value of our assets for purposes of the PFIC determination may be affected by the trading value of our Common Shares, which could fluctuate significantly. The total value of our assets for purposes of the PFIC asset test frequently (though not invariably) may be inferred using the market price of our ordinary shares, which may fluctuate considerably and thereby affect the determination of our PFIC status for future taxable years. Our U.S. counsel expresses no opinion with respect to our PFIC status for the current or future taxable years. We will endeavor to determine our PFIC status for each taxable year and make such determination available to U.S. holders.

The determination of our PFIC status is impacted by structures and arrangements we have implemented that are intended in part 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, the 2021 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. For example, as discussed above, the Look-Through Rule generally applies with respect to our 25% or more owned subsidiaries. If we are subject to the accumulated earnings tax (or waive any benefit under any treaty which would otherwise prevent the imposition of such tax) and we own at least 25% (by value) of the stock of a U.S. corporation (a “25%-owned U.S. corporation”), then for purposes of determining our PFIC status, generally any stock of a U.S. corporation (such corporation, a “second-tier U.S. corporation,” and such stock, “qualified stock”) held by such 25%-owned U.S. corporation shall be treated as an asset which does not produce passive income (and is not held for the production of passive income) and any amount included in gross income with respect to such stock shall not be treated as passive income (the “Look-Through Rule Exception”). Accordingly, since we have waived any benefit under any treaty which would otherwise prevent the imposition of the accumulated earnings tax, we expect that the Look-Through Rule Exception applies to us and, for purposes of determining our PFIC status, any qualified stock held by our subsidiaries that are 25%-owned U.S. corporations are expected not to be treated as passive assets and any amount included in gross income with respect to such stock are expected not to be treated as passive income. Though we expect that the Look-Through Rule Exception applies to us, such determination, however, is subject to uncertainties. For example, the 2021 Regulations adopted an anti-abuse rule with respect to the application of the Look-Through Rule Exception. According to the anti-abuse rule, the Look-Through Rule Exception will not apply if a principal purpose for the formation of, acquisition of, or holding of stock of the 25%-owned U.S. corporation or the second-tier U.S. corporation, or for the capitalization or other funding of the second-tier U.S. corporation, is to hold passive assets through the second-tier U.S. corporation to avoid classification of the foreign corporation as a PFIC. While we do not believe that such anti-abuse rule will apply to us in light of the legislative history of the Look-Through Rule Exception as well as the nature and composition of our income and the nature, composition and value of our assets, there is no assurance regarding the application of the anti-abuse rule with respect to our PFIC status in our past, current, or future taxable years.

Investors who are U.S. holders are urged to consult their own tax advisors regarding the application of the Look-Through Rule, the Look-Through Rule Exception, and the anti-abuse rule.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.1#†	License and Collaboration Agreement dated as of November 21, 2022	—	—	—	Filed herewith
10.2#†	Investor Rights Agreement dated as of November 21, 2022	—	—	—	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 13, 2023

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.**

LICENSE AND COLLABORATION AGREEMENT

by and between

PFIZER INC.

and

[*]**

DATED AS OF NOVEMBER 21, 2022

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***]

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (“**Agreement**”) is dated as of the 21st day of November, 2022 (the “**Effective Date**”), by and between Pfizer Inc., a corporation organized and existing under the laws of Delaware with offices at [***] (“**Pfizer**”), [***] a corporation organized and existing under the laws of Delaware with offices at [***] (“**Licensee**”), and solely with respect to Section 11.4, Roivant Sciences Ltd., a corporation organized and existing under the laws of Bermuda with offices at [***] (“**Roivant**”). Licensee and Pfizer (and, solely with respect to Section 11.4, Roivant) may, from time-to-time, be individually referred to as a “**Party**” and collectively referred to as the “**Parties**”.

RECITALS

WHEREAS, Pfizer Controls the Licensed Technology (hereinafter defined); and

WHEREAS, Licensee wishes to obtain, and Pfizer wishes to grant, certain licenses under the Licensed Technology on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS.

1.1 “**AAA**” is defined in Section 18.3.3.

1.2 “**Accounting Standard**” means International Financial Reporting Standards (IFRS) or U.S. Generally Accepted Accounting Principles (GAAP), as generally and consistently applied by the applicable entity in accordance with Applicable Law.

1.3 “**Affiliate**” means, with respect to a Party, as of the applicable point in time and for so long as the applicable relationship exists, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, the definition of Excluded Affiliate, and Sections 12.4 and 12.5, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” shall refer to: (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of an entity, whether through the ownership of voting securities or other ownership interest, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of such entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity. Notwithstanding the foregoing, an Excluded Affiliate will not be deemed an Affiliate of Licensee for any purpose under this Agreement.

1.4 “**Agreement**” is defined in the introduction to this Agreement.

1.5 “**Alliance Manager**” is defined in Section 5.2.1.

1.6 “**Anti-Corruption Laws**” means applicable international, national, state and local laws, statutes, rules and regulations regarding corruption and bribery, including laws that prohibit the corrupt payment, offer, promise, or authorization of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any Government Official, commercial entity, or any other Person to obtain an improper business advantage, including the Foreign Corrupt Practices Act (15 U.S.C. §78-dd-1, et seq.), the UK Bribery Act of 2010, and laws implementing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions; each as may be amended or supplemented from time to time.

1.7 “**Antibody Product**” is defined in Section 1.110.

1.8 “**Applicable Law**” means any applicable United States federal, state or local law, or foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution, or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination, or award entered by or with any Governmental Authority, or any license, franchise, permit, or similar right granted under any of the foregoing, or any similar provision having the force or effect of law, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.), the Public Health Service Act (42 U.S.C. § 201, et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), the Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state and foreign statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA, EMA and any other comparable foreign Regulatory Authority and all applicable Anti-Corruption Laws, accounting and recordkeeping laws, and laws relating to interactions with Healthcare Professionals and Government Officials. For the avoidance of doubt, any specific references to any Applicable Law or any portion thereof shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, order, writ, judgment, injunction, decree, stipulation, ruling, or determination thereto.

1.9 “**Bankruptcy Code**” is defined in Section 15.7.

1.10 “**Biosimilar Competition**” means with respect to a Product that is a “reference product” as such term is used in Section 351(i)(4) of the Public Health Service Act or an equivalent under its foreign equivalent (the “**Reference Product**”) in a particular country in the Territory, [***].

1.11 “**Biosimilar Product**” means, in a particular country with respect to a Reference Product regulated as a biological medicinal product, any biological medicinal product that: (a) has received all necessary approvals and licensures by the applicable Regulatory Authorities in such country to market and sell such product as a biosimilar or interchangeable product with respect to such Product; (b) is marketed or sold under a Regulatory Approval granted to a Third Party by a Regulatory Authority, *provided* such Third Party (i) is not a licensee or sublicensee of Product and (ii) does not purchase such product in a chain of distribution that includes Licensee or its Affiliates or Pfizer; and (c) is approved by the applicable Regulatory Authority as (i) a “biosimilar” or “interchangeable biosimilar” with respect to such Product, (ii) a “similar biological medicinal product” with respect to which Product is the “reference medicinal product,” or (iii) if not in the United States or E.U., as the foreign equivalent of a “biosimilar,” “interchangeable,” or “similar biological medicinal product” with respect to Product; in each case ((c)(i)-(iii)), for use in such country pursuant to an abbreviated regulatory approval process governing approval of biosimilars based on the then-current standards for regulatory approval in such country.

1.12 [***]

1.13 [***]

[***]

1.14 [***]

1.15 [***]

1.16 [***]

1.17 [***]

1.18 [***]

1.19 [***]

1.20 [***]

1.21 [***]

1.22 “**BLA**” means, with respect to a biological product, a Biologics License Application submitted to the FDA in accordance with Section 351 of the Public Health Service Act (42 U.S.C. § 262), the FD&C Act, 21 C.F.R. § 601.2, or any analogous application or submission with any Regulatory Authority outside of the United States for the purpose of obtaining Regulatory Approval to market and sell the product, including, an application with the EMA pursuant to Article 6 of Regulation (EC) No 726/2004 and Article 10(4) of Directive 2001/83/EC for the purpose of obtaining Regulatory Approval to market and sell the product in the E.U.

1.23 “**BPCIA**” means the Biologics Price Competition and Innovation Act, codified at Pub. L. NO. 111-148, §§ 7001–7003, 124 Stat. 119, 804–23 (2010).

1.24 “**Business**” is defined in Section 12.2.22.

1.25 “**Business Day**” means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York or London, United Kingdom are authorized or required by Applicable Law to remain closed.

1.26 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, except that the first Calendar Quarter of the Term commences on the Effective Date and ends on the first to occur of March 31, June 30, September 30 and December 31 after the Effective Date, and the last Calendar Quarter of the Term ends on the last day of the Term.

1.27 “**Calendar Year**” means the period of twelve (12) consecutive calendar months ending on December 31, except that the first Calendar Quarter of the Term commences on the Effective Date and ends on December 31 of the year in which the Effective Date occurs, and the last Calendar Year of the Term commences on January 1 of the year in which the Term ends and ends on the last day of the Term.

1.28 [***]

1.29 “**CDA**” means that certain Confidential Disclosure Agreement, by and between Pfizer and Roivant Sciences, Inc., dated [***].

1.30 “**CDO**” means a contract development organization.

1.31 “**Change of Control**” means, with respect to a Party, whether effected in a single transaction or a series of related transactions, [***].

1.32 “**Clinical Trial**” means those studies in human subjects that are required by Applicable Law, or otherwise recommended or required by the Regulatory Authorities or reasonably useful, to obtain or maintain any Regulatory Approval for a Product for one (1) or more indications.

1.33 “**Closing**” is defined in Section 3.1.

1.34 “**CMC**” means chemistry, manufacturing and controls.

1.35 “**CMO**” means a contract manufacturing organization.

1.36 [***]

1.37 “**Code**” means the U.S. Internal Revenue Code of 1986, as amended.

1.38 [***]

1.39 [***]

1.40 “**Commercialize**” or “**Commercialization**” means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize an antibody or product. When used as a noun, “**Commercialization**” means any and all activities involved in Commercializing.

1.41 “**Commercially Reasonable Efforts**” means, with respect to the Development or Commercialization of a TL1A Antibody or Product in or for a particular country, [***]

1.42 [***]

1.43 “**Confidential Information**” means the existence, terms and provisions of this Agreement and all other proprietary information and data of a financial, commercial or technical nature that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates. [***] Confidential Information shall not include information that: (a) is, at the time of disclosure or becomes, after the time of disclosure, known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information; (b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party to the receiving Party; (c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or (d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use of or access to the Confidential Information.

1.44 “**Control**” or “**Controlled**” means, with respect to any Intellectual Property Rights or other rights to provide data or other information, the legal authority or right (whether by ownership, license or otherwise, other than any license granted pursuant to this Agreement) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights to the other Party or provide such data or other information to such other Party without breaching the terms of any agreement with a Third Party.

1.45 “**Cover**” or “**Covered**” means, with respect to a given TL1A Antibody or Product and a given Valid Claim of a Licensed Patent Right, that the Exploitation of such TL1A Antibody or Product would, but for the licenses granted by Pfizer to Licensee under this Agreement, infringe such Valid Claim.

1.46 “**CRO**” means a contract research organization.

1.47 “**CSO**” means a contract sales organization.

1.48 [***]

1.49 “**Develop**” or “**Developing**” means to discover, research or otherwise develop a process, antibody or product, including conducting non-clinical and clinical research and development activities directed to, necessary, reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, including fulfilling post-approval regulatory obligations. When used as a noun, “**Development**” means any and all activities involved in Developing.

1.50 “**Development Plan**” is defined in Section 5.7.

1.51 “**Disclosure Letter**” is defined in Section 2.3.8.

1.52 “**Effective Date**” is defined in the introduction to this Agreement.

1.53 “**EMA**” means the European Medicines Agency or any successor agency thereto.

1.54 “**E.U.**” means any of the 27 countries comprising the European Union as of the Effective Date, any additional member countries from time to time, and the United Kingdom.

1.55 “**Excluded Action**” is defined in Section 18.3.7.

1.56 “**Excluded Affiliate**” means (a) [***]. For clarity, a Person may cease to be or may become an Excluded Affiliate from time to time if its status changes such that it ceases to satisfy or satisfies the requirements of an Excluded Affiliate hereunder.

1.57 “**Existing Pfizer Affiliates**” means the Affiliates of Pfizer existing as of the Effective Date.

1.58 “**Exploit**” or “**Exploitation**” means to Develop, Manufacture or Commercialize, or to otherwise make, use, offer to sell, sell or import, an antibody or product. When used as a noun, “**Exploitation**” means any and all activities involved in Exploiting.

1.59 “**FD&C Act**” means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended, and the rules and regulations promulgated thereunder.

1.60 “**FDA**” means the United States Food and Drug Administration or any successor federal agency thereto.

1.61 “**Fees**” means (a) in the case of Pfizer, any and all Licensee Royalties, and (b) in the case of Licensee, any and all Pfizer Royalties.

1.62 “**Field**” means the treatment, prevention, diagnosis, control and maintenance of all indications in humans.

1.63 “**First Commercial Sale**” means the first sale of a Product by Licensee or Licensee’s Affiliate or sublicensee to a Third Party in a country in the Territory following receipt of Regulatory Approval for such Product in such country. Dispositions of Product, or use of Product in, clinical trials or other scientific testing, as free samples, or under expanded access programs or for charitable purposes shall not be considered a First Commercial Sale.

1.64 “**First Reporting Window**” is defined in Section 5.5.1.

1.65 “**Fraud**” means, with respect to any Person, a deliberately fraudulent misrepresentation with respect to the making of the representations and warranties specifically set forth in Section 12, as applicable, with the actual knowledge by such Person that such representations and warranties made pursuant to Section 12 (each as qualified by the Disclosure Schedules), as applicable, were untrue when made, with the specific intention that a Party to this Agreement rely thereon to its detriment and such Party did in fact rely thereon to such Party’s detriment; *provided, however*, that in no event shall the knowledge of any Person be imputed to any other Person.

1.66 “**FTE**” means the efforts of one or more employees of a Party (or its Affiliate) equivalent to the efforts of one full-time employee for one year, or in the case of less than a full-time dedicated person, a full-time equivalent person-year based upon a total of eighteen hundred (1800) hours per year of work.

1.67 [***]

1.68 “**Global Regulatory Filings**” means [***].

1.69 “**Global Trade Control Laws**” means the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the U.S. economic sanctions rules and regulations implemented under statutory authority or the President’s Executive Orders and administered by the U.S. Department of the Treasury Office of Foreign Assets Control; E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012; other E.U. Council sanctions regulations, as implemented in E.U. Member States; United Nations sanctions policies; all relevant regulations and legislative instruments made under any of the above; other applicable economic sanctions, export and import control laws, and other applicable laws, regulations, legislation, Orders and requirements imposed by a relevant Governmental Authority.

1.70 “**GMP**” means all applicable requirements, standards, practices, and procedures for current good manufacturing practices for pharmaceuticals and biologics promulgated by the FDA, including those included in the FD&C Act and 21 C.F.R. Parts 210, 211, 600-680, and 820, as the same may be amended from time to time, and such standards of good manufacturing practice as are required by the Regulatory Authorities of the E.U. and other organizations and Governmental Authorities in countries in which the applicable Product is intended to be manufactured or sold, to the extent such standards are not less stringent than United States GMP.

1.71 “**Good Clinical Practices**” means the FDA’s requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials contained in 21 C.F.R. Parts 50, 54, 56, 58 and 312, or those equivalent standards applicable in the relevant jurisdiction.

1.72 “**Good Laboratory Practices**” means the FDA’s requirements for conducting non-clinical laboratory studies contained in 21 C.F.R. Part 58, and those equivalent requirements applicable in any relevant jurisdiction.

1.73 “**Government**” or “**Governmental Authority**” is broadly interpreted and includes: (a) any national, federal, state, local, regional, or foreign government, or level, branch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or -controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; and (g) any political party.

1.74 “**Government Official**” is broadly interpreted and includes: (a) any elected or appointed Government official (e.g., a legislator or a member of a ministry of health); (b) any employee or person acting for or on behalf of a Government, a Government department or agency, an institution or entity owned or controlled by a Government (e.g., a Healthcare Professional employed by a Government-owned or -controlled hospital, or a person serving on a healthcare committee that advises a Government), or an enterprise or instrumentality performing a governmental function; (c) any candidate for public office, or officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization (e.g., the United Nations, the Red Cross, or the World Bank); (e) any member of a military or a royal or ruling family; and (f) any person otherwise categorized as a Government official under Applicable Law.

1.75 “**HCP**” or “**Healthcare Professional**” includes any physician, nurse, pharmacist, or other person who may administer, prescribe, purchase, or recommend pharmaceutical products or other healthcare products.

1.76 “**Healthcare Laws**” means the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the FD&C Act, the Controlled Substances Act (21 U.S.C. §§ 801 et seq.), Section 1128G of the Social Security Act (the Physician Payment Sunshine Law), The Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1, et seq.), the Medicare Program (Title XVIII of the Social Security Act), the Medicaid Program (Title XIX of the Social Security Act), the regulations promulgated pursuant to such laws, requirements of the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, requirements of Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126), state pharmaceutical assistance programs and regulations under such laws, and Good Clinical Practices, Good Laboratory Practices, and GMP.

1.77 “**IND**” means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of a TL1A Antibody or a Product pursuant to 21 C.F.R. Part 312, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.78 “**Indemnified Party**” is defined in Section 13.3.

1.79 “**Indemnifying Party**” is defined in Section 13.3.

1.80 “**Intellectual Property Rights**” means all trade secrets, copyrights, Patent Rights, Trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.81 “**Intended Tax Treatment**” is defined in Section 7.10.5.

1.82 [***]

1.83 “**Joint Developed IP**” means [***].

1.84 “**Know-How**” means any proprietary invention, discovery, development, data, information, process, method, technique or other know-how, whether or not patentable.

1.85 “**Knowledge**” means actual knowledge of the individuals listed on Schedule 1.85 and is not meant to require or imply that any particular inquiry or investigation has been undertaken, including obtaining any type of search (independent of that performed by the actual Governmental Authority during the normal course of patent prosecution, as applicable, in a jurisdiction) or opinion of counsel.

- 1.86** “**Licensed Know-How**” means Know-How Controlled by Pfizer or any of the Existing Pfizer Affiliates [***].
- 1.87** “**Licensed Patent Rights**” [***].
- 1.88** “**Licensed Technology**” means, collectively, the Licensed Patent Rights and Licensed Know-How.
- 1.89** “**Licensee**” is defined in the introduction to this Agreement.
- 1.90** “**Licensee Developed IP**” means any Intellectual Property Rights that are [***].
- 1.91** [***]
- 1.92** “**Licensee Indemnitees**” is defined in Section 13.2.
- 1.93** [***]
- 1.94** “**Licensee Product Trademarks**” is defined in Section 9.4.1.
- 1.95** “**Licensee Quarter**” means each of the four (4) thirteen (13) week periods commencing on April 1 of any Licensee Year, consistently applied.
- 1.96** “**Licensee Royalties**” is defined in Section 7.2.1.
- 1.97** “**Licensee Royalty Rate**” is defined in Section 7.2.1.
- 1.98** “**Licensee Third Party License**” is defined in Section 7.3.2(a).
- 1.99** “**Licensee Year**” means the twelve-month fiscal periods observed by Licensee commencing on April 1 and ending March 31, consistently applied.
- 1.100** [***]
- 1.101** “**Losses**” means, subject to Section 14.1, losses, damages, liabilities, payments, fines, fees, penalties, charges, judgments, settlement payments and costs and expenses including interest penalties and reasonable attorneys’ fees and expenses.

1.102 “Major European Market Country” means [***]. The “Major European Market Countries” means, [***]

1.103 “Manufacture” or “Manufacturing” means to make, have made, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store an antibody or product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing an antibody or product or any component thereof.

1.104 [***]

1.105 [***]

1.106 [***]

1.107 [***]

1.108 [***]

1.109 [***]

1.110 “Net Sales” means, [***].

- 1.112 “**Occurrence**” is defined in Section 12.4.6.
- 1.113 “**Ongoing Clinical Trial Costs**” is defined in Section 5.9.2.
- 1.114 “**Ongoing Clinical Trials**” mean those Clinical Trials of the Products that are ongoing as of the Effective Date and set forth on Schedule 1.114.
- 1.115 “**Option**” is defined in Section 2.3.3.
- 1.116 “**Option Effective Date**” is defined in Section 2.3.5(a).
- 1.117 “**Option Exercise Notice**” is defined in Section 2.3.4.
- 1.118 “**Option Information Delivery Date**” is defined in Section 2.3.2.
- 1.119 “**Option Period**” is defined in Section 2.3.2.
- 1.120 “**Order**” means any writ, judgment, order, decree, injunction, decision, verdict, award or ruling or other binding obligation of, or settlement or other similar agreement with, any Governmental Authority.
- 1.121 “**Other Active Ingredient(s)**” is defined in Section 1.110.
- 1.122 “**Party**” and “**Parties**” is defined in the introduction to this Agreement.
- 1.123 “**Patent Rights**” means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, divisions, continuations, substitutions, continuations-in-part and renewals, and all patents granted thereon, (c) patents-of-addition, re-examinations, reissues and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, pediatric exclusivity, Patent Term Extensions or the equivalent thereof, (d) inventor’s certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.
- 1.124 “**Patent Term Extension**” is defined in Section 9.3.4.
- 1.125 “**Permitted Contractor**” means a CMO, CRO, CSO, distributor or wholesaler, in each case, that is providing services on behalf of Licensee on a fee-for-service basis in connection with the Development, Commercialization or Manufacture of any TL1A Antibody or Product.
- 1.126 “**Person**” means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.
- 1.127 “**Pfizer**” is defined in the introduction to this Agreement.

- 1.128** “Pfizer Developed IP” means [***].
- 1.129** “Pfizer Election Notice” is defined in Section 9.3.5.
- 1.130** “Pfizer Indemnitees” is defined in Section 13.1.
- 1.131** “Pfizer Product Trademarks” is defined in Section 9.4.1.
- 1.132** “Pfizer Quarter” means each of the four (4) thirteen (13) week periods commencing on December 1 of any Pfizer Year, consistently applied.
- 1.133** “Pfizer Royalties” is defined in Section 7.2.2.
- 1.134** “Pfizer Royalty Rate” is defined in Section 7.2.2.
- 1.135** “Pfizer Third Party License” is defined in Section 7.3.2(b).
- 1.136** “Pfizer Year” means the twelve-month fiscal periods observed by Pfizer commencing on December 1 with respect to any country in the ROW, consistently applied.
- 1.137** “Pharmacovigilance Agreement” is defined in Section 5.8.
- 1.138** “Phase 1 Clinical Trial” means a Clinical Trial that generally provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a) (or its foreign equivalent), as amended (or its successor regulation), *provided, however*, a Phase 1 Clinical Trial does not include any study generally characterized by the FDA as an “exploratory IND study” in CDER’s Guidance for Industry, Investigators, and Reviewers Exploratory IND Studies, January 2006, irrespective of whether or not such study is actually performed in the United States or under an IND.
- 1.139** “Phase 2 Clinical Trial” means a Clinical Trial of a pharmaceutical or biological product conducted under a valid and effective IND and institutional review board approval (or foreign equivalent), the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical or biological product is safe for its intended use, to evaluate the product’s efficacy for a particular indication(s) in patients with the disease or condition for which the product is intended, and to obtain sufficient information about such product’s efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b) (or its foreign equivalent), as amended (or its successor regulation), to permit the design of further Clinical Trials, or, with respect to any other country or region, the equivalent of such Clinical Trial in such other country or region.

1.140 “**Phase 3 Clinical Trial**” means a Clinical Trial with a defined dose or a set of defined doses of a pharmaceutical or biological product conducted under a valid and effective IND and institutional review board approval (or foreign equivalent), designed to ascertain evidence of efficacy and safety of such product for a particular indication(s) in patients with the disease or condition for which the product is intended, in a manner that is generally consistent with 21 CFR § 312.21(c) (or its foreign equivalent), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of a BLA for Regulatory Approval, or, with respect to any other country or region, the equivalent of such Clinical Trial in such other country or region.

1.141 [***]

1.142 “**Pricing and Reimbursement Approval**” means [***].

1.143 “**Priority Review Voucher**” means a “Section 529” US priority review voucher issued by the United States Department of Health and Human Services that entitles the holder of such voucher to Priority Review of a single human drug application submitted under Section 505(b)(1) of the Act or Section 351(a) of the United States Public Health Service Act, as further defined in Section 529(a)(2) of the Act (21 U.S.C. § 360ff(a)(2)).

1.144 “**Product**” means each product, dosage, substance or formulation, for use in the Field, that incorporates or is comprised of (alone or as a Combination Product) the TL1A Antibody.

1.145 “**Purchase Agreement**” means the Stock Purchase Agreement entered into by [***] Roivant and Pfizer and dated as of the date hereof.

1.146 “**Recipients**” is defined in Section 11.1.

1.147 “**Reference Product**” is defined in Section 1.10.

1.148 “**Regulatory Approval**” means, with respect to a Product in any country or jurisdiction, any approval, registration, license or authorization that is required by the applicable Regulatory Authority to market and sell such Product in such country or jurisdiction, including any Pricing and Reimbursement Approvals.

1.149 “**Regulatory Authority**” means, with respect to a particular country or jurisdiction, any Governmental Authority responsible for reviewing or granting Regulatory Approvals for a Product in such country or jurisdiction in the Territory.

1.150 “**Regulatory Exclusivity**” means exclusive marketing rights conferred by any Regulatory Authority with respect to a Product that prevents the Regulatory Authority from accepting or approving an application pursuant to [***].

1.151 “**Regulatory Filings**” means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application, including any IND, BLA, exclusivity requests, any submission to a regulatory advisory board, any marketing authorization application, any documentation for customs authorities, and any supplement or amendment thereto. In addition, Company Core Data Sheets shall be deemed “Regulatory Filings” for purposes of Section 5.4.

1.152 “**Regulatory Transfer Activities**” is defined in Section 2 of Schedule 4.

1.153 “**Relevant Records**” is defined in Section 8.1.

1.154 “**Report**” is defined in Section 5.5.1.

1.155 “**Reporting Category**” is defined in Section 5.5.1.

1.156 [***]

1.157 “**Residuals**” means information in non-tangible form that is retained in the unaided memory of persons who have had access to any TL1A Antibody, Products or Licensed Technology prior to the Effective Date, including ideas, concepts, Know-How or techniques contained therein, but not including any ideas, concepts, Know-How, or techniques to the extent Covered by a Valid Claim in any Licensed Patent Right. A person’s memory will be considered to be unaided if the person has not intentionally memorized the information for the purpose of retaining and subsequently using or disclosing it.

1.158 “**Restricted Market**” means, as applicable under Global Trade Control Laws, the Crimean Peninsula, Cuba, Iran, North Korea, and Syria.

1.159 “**Restricted Party**” means any individual or entity on any of the following “**Restricted Party Lists**”: the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities, as published by the U.S. Health and Human Services – Office of Inspector General; any lists of prohibited or debarred parties established under the FD&C Act; the list of persons and entities suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Authorities of the countries that have jurisdiction over the activities conducted under this Agreement.

1.160 “**Review Period**” is defined in Section 16.3.

1.161 “**Roivant**” is defined in the introduction to this Agreement.

1.162 “**ROW**” means the Territory, excluding the United States and Japan.

1.163 [***]

1.164 “**Royalty Term**” means, with respect to each Product in each country in the Territory or ROW, as applicable, the period commencing on the First Commercial Sale of such Product in such country and expiring upon the later of: (a) [***] years following the date of First Commercial Sale of such Product in such country, (b) the expiration of all Regulatory Exclusivity provided by an applicable Governmental Authority for such Product in such country and (c) the date upon which the use, sale, offer for sale or importation of such Product in such country would no longer infringe, but for the license granted herein, a Valid Claim of a Licensed Patent Right.

1.165 “**SDNY**” is defined in Section 18.3.8.

1.166 “**SEC**” is defined in Section 12.2.22.

1.167 [***]

1.168 [***]

1.169 “**Significant Violation**” means conduct that a reasonable person would consider a probable violation of applicable policies or procedures designed to ensure compliance with Applicable Laws, which may result in significant or substantial liability if a Governmental Authority determined such conduct to be a violation of Applicable Law.

1.170 “**Subsidiary**” means, with respect to any Person, any other Person with respect to which such first Person (a) possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the beneficial ownership of voting securities, by contract or otherwise or (b) beneficially owns at least fifty percent (50%) of the aggregate ordinary voting power of such Person.

1.171 “**Tax Action**” is defined in Section 7.10.2.

1.172 “**Tax Credit**” is defined in Section 7.10.3.

1.173 “**Tax Payment**” is defined in Section 7.10.3.

1.174 “**Term**” is defined in Section 15.1.

1.175 “**Terminated Territory**” means each country with respect to which this Agreement is terminated by either Party pursuant to Section 15.2.

1.176 “**Territory**” means worldwide, other than any Terminated Territory.

1.177 “**Third Party**” means any Person other than a Party or an Affiliate of a Party.

1.178 “**Third Party Infringement**” is defined in Section 10.1.

1.179 [***]

1.180 [***]

1.181 “**TL1A**” means [***].

1.182 “**TL1A Antibody**” means [***].

1.183 “**Trademark**” means trademarks, service marks, certification marks, trade dress, internet domain names, trade names, identifying symbols, designs, product names, company names, slogans, logos or insignia, whether registered or unregistered, and all common law rights, applications and registrations therefor, and all goodwill associated therewith.

1.184 “**Transaction Agreements**” means (a) this Agreement, [***] (d) that certain Investor Rights Agreement [***] and (e) each other agreement or certificate to be delivered by any Party hereto at the Closing contemplated hereby.

1.185 “**Transfer Tax**” is defined in Section 7.10.1(b).

1.186 [***]

1.187 [***]

1.188 [***]

1.189 “**United States**” or “**U.S.**” means the United States of America and its territories and possessions.

1.190 “**Valid Claim**” means with respect to a particular country, a claim of a Patent Right within the Licensed Patent Rights that [***] (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and (ii) has not expired or been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise [***].

1.191 “**VAT**” is defined in Section 7.10.1(c).

1.192 “**Working Group**” is defined in Section 6.3.6.

1.193 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to all genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) 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), (e) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules shall be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

2. LICENSE GRANT.

2.1 License Grant to Licensee.

2.1.1 Licensed Patent Rights and Pfizer Developed IP. Subject to the terms and conditions of this Agreement, including Pfizer's retained rights set forth in Section 2.5, Pfizer hereby grants to Licensee (a) an exclusive (even as to Pfizer and its Affiliates, except as otherwise provided in Section 2.5), sublicensable, through multiple tiers (subject to Section 2.2), royalty-bearing right and license (or sublicense) under the Licensed Patent Rights to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, and have Commercialized the TL1A Antibody and Products in the Field within the Territory, and (b) a non-exclusive, sublicensable, through multiple tiers, royalty-bearing right and license under the Pfizer Developed IP to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, and have Commercialized the TL1A Antibody and Products in the Field within the Territory. Pfizer shall use commercially reasonable efforts to promptly disclose to Licensee all Pfizer Developed IP and Joint Developed IP during the Term.

2.1.2 Licensed Know-How. Subject to the terms and conditions of this Agreement, Pfizer hereby grants to Licensee a non-exclusive, sublicensable, through multiple tiers (subject to Section 2.2), royalty-bearing right and license (or sublicense) to use the Licensed Know-How to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit the TL1A Antibody and Products in the Field within the Territory.

2.1.3 Diagnostic License. Subject to the terms and conditions of this Agreement, Pfizer hereby grants to Licensee a non-exclusive, fully paid up, non-royalty bearing, sublicensable, in multiple tiers (subject to Section 2.2) right and license under the Licensed Technology and Pfizer Developed IP to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized, and otherwise Exploit any diagnostic related to TL1A (including any diagnostic product intended to support identification of potential patients for treatment using the TL1A Antibody or any Product) in the Field within the Territory.

2.1.4 Affiliates. To the extent any of the Licensed Technology is Controlled by an Existing Pfizer Affiliate, then promptly following the Effective Date, Pfizer shall cause such Existing Pfizer Affiliate to take all necessary actions to give effect to the licenses granted under this Section 2.1, and carry out the other obligations of Pfizer hereunder (including under Section 9.2 and Section 10.2).

2.1.5 Wrong Pockets. [*]**

2.2 Sublicense Rights. [*]** Licensee may sublicense the rights granted to it by Pfizer under Sections 2.1.1 and 2.1.2, through multiple tiers, without Pfizer's approval. Any and all sublicenses shall be subject to the following requirements:

2.2.1 [*]**

2.2.2 All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement and [***] preclude the granting of further sublicenses in contravention with the terms and conditions of this Agreement.

2.2.3 In no event shall any sublicense relieve Licensee of any of its obligations under this Agreement.

2.2.4 [***]

In addition, Sections 2.2.1, 2.2.3, and 2.2.4 shall apply to sublicenses granted by Pfizer under the rights granted by Licensee to Pfizer hereunder, *mutatis mutandis*.

2.3 Option to [*]**

[***]

2.4 License Grant to Pfizer.

2.4.1 Subject to the terms and conditions of this Agreement, Licensee hereby grants to Pfizer (a) an exclusive (even as to Licensee and its Affiliates), sublicensable, through multiple tiers, royalty-bearing right and license under the Licensed Patent Rights to Commercialize and have Commercialized the TL1A Antibody and Products in the Field in the ROW, and (b) a non-exclusive, sublicensable, through multiple tiers, royalty-bearing right and license under the Licensee Developed IP to Commercialize and have Commercialized the TL1A Antibody and Products in the Field in the [***]. Licensee shall use reasonable best efforts to promptly disclose to Pfizer all Licensee Developed IP and Joint Developed IP during the Term.

2.4.2 Subject to the terms and conditions of this Agreement, Licensee hereby grants to Pfizer a non-exclusive, fully paid up, non-royalty bearing, sublicensable, in multiple tiers right and license under the Licensee Developed IP to Commercialize and have Commercialized any diagnostic related to TL1A (including any diagnostic product intended to support identification of potential patients for treatment using the TL1A Antibody or any Product) in the Field in the ROW.

2.5 Retained Rights. [*]**

2.6 Residuals. Pfizer may use for any purpose the Residuals resulting from access to or work with any TL1A Antibody, Product or Licensed Technology; *provided* that, for the avoidance of doubt, this Section 2.6 shall not constitute a grant back of the license and rights granted to Licensee under the Licensed Patent Rights pursuant to Section 2.1.1 or a license or other rights under any Patent Right Controlled by Licensee. Any use made by the Pfizer of any such Residuals is on an “as is, where is” basis, with all faults and all representations and warranties disclaimed and at Pfizer’s sole risk.

2.7 No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon Licensee by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of Pfizer or its Affiliates other than the rights in Licensed Technology expressly granted herein, regardless of whether such technology or Intellectual Property Rights shall be dominant or subordinate to any Licensed Technology.

3. CLOSING.

3.1 Closing. The closing of the transactions contemplated by this Agreement (the “**Closing**”) shall take place remotely via the exchange of documents and signature pages on the date hereof.

3.2 Closing [***] Deliverables.

3.2.1 Closing Deliverables and Actions by Pfizer. At the Closing, Pfizer shall deliver, or cause to be delivered, to Licensee the following:

(a) each of the Transaction Agreements duly executed by Pfizer or the applicable Pfizer Affiliate that is a party thereto.

3.2.2 Closing Deliverables and Actions by Licensee. At the Closing, Licensee shall deliver, or cause to be delivered, to Pfizer the following:

(a) a duly executed certificate by the Secretary of Licensee certifying as to: (i) the full force and effect of the articles of incorporation and bylaws (or equivalent governing documents) of Licensee attached to such certificate as an exhibit, (ii) the accuracy and full force and effect of resolutions adopted by the board of directors of Licensee approving the transactions contemplated by the Transaction Agreements, attached to such certificate as an exhibit, and (iii) the good standing of the Licensee in its jurisdiction of formation, with a certificate of good standing from such jurisdiction dated no more than [***] prior to the Effective Date, attached to such certificate as an exhibit; and

(b) each of the Transaction Agreements duly executed by Licensee or the applicable Licensee Affiliate that is a party thereto.

3.2.3 [***]

4. **TRANSFER ACTIVITIES.** Schedule 4 sets forth the documentation, materials and Licensed Know-How that Pfizer will transfer to Licensee or its designee and related activities and services to be performed by the Parties. If there is an inconsistency between Schedule 4 and this Agreement, the terms of this Agreement shall prevail.

5. **DEVELOPMENT; REGULATORY; MANUFACTURING.**

5.1 General. Except as set forth on Schedule 4 or as otherwise expressly set forth in this Section 5, as between the Parties, Licensee shall have sole responsibility for [***], and the sole authority over and control of, the Development, Manufacture and Regulatory Approval of the TL1A Antibody and Products in the Field in the Territory.

5.2 Alliance Management.

5.2.1 Alliance Managers. Within [***] following the Effective Date, each Party will designate (by written notice to the other Party) a single individual to act as its alliance manager under this Agreement to conduct the activities described below in Section 5.2.2 (each, an “**Alliance Manager**”). Each Party may change the person designated as its Alliance Manager upon written notice (including via email notification) to the other Party.

5.2.2 Roles and Responsibilities. The Alliance Managers will serve as the primary contact point between the Parties for the activities under this Agreement for the purpose of providing each Party with information on the progress of Development and Commercialization of the Products and shall have the following responsibilities:

[***]

(e) perform such other functions as agreed by the Parties.

5.3 Diligence. Licensee shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to [***] (collectively, the “**Development Commitments**”).

5.4.1 General. In connection with its efforts to Develop the Products, as between the Parties, Licensee shall bear all responsibility [***] for submitting Regulatory Filings and obtaining and, subject to Section 5.4.6, maintaining Regulatory Approval for the Products in the Territory, subject to such Regulatory Transfer Activities to be performed by Pfizer as set forth in Section 2 of Schedule 4. For clarity, the terms and conditions contained in this Section 5.4 are subject to those contained in Section 5.9.

5.4.2 U.S. and Japan Review Rights. Licensee will own all Regulatory Filings, Regulatory Approvals, and related regulatory documents for the Products for the U.S. and Japan. Licensee shall provide Pfizer with a reasonable opportunity to review and comment on all material Regulatory Filings relating to all Products submitted to the FDA, as well as all Global Regulatory Filings, by or on behalf of Licensee during the Term. Licensee shall promptly provide Pfizer with access to key correspondence with the FDA relating to Products. For clarity, [***].

5.4.3 ROW Review Rights. Notwithstanding Section 5.4.1, and except with respect to Global Regulatory Filings which are covered by Section 5.4.2, Licensee shall provide Pfizer with an opportunity to review and comment on all material Regulatory Filings in the ROW prior to submission to the applicable Regulatory Authority. Licensee shall provide access to interim drafts of such material Regulatory Filings to Pfizer, and Pfizer shall provide its comments on the near final drafts of such material Regulatory Filings or of proposed material actions within [***], or such other longer period of time mutually agreed to by the Parties. In the event that a Regulatory Authority establishes a response deadline for any such material Regulatory Filing or material action shorter than such [***] period, the Parties shall work cooperatively to ensure that Pfizer has a reasonable opportunity for review and comment within such deadlines. Licensee shall, [***].

5.4.4 ROW Information Rights. Subject to the immediately following sentence, Licensee shall provide Pfizer with (a) access to or copies of all material written or electronic correspondence (other than Regulatory Filings) relating to the Development or Commercialization of the TL1A Antibody or Products received by Licensee or its Affiliates or sublicensees from, or forwarded by Licensee or its Affiliates or sublicensees to, the Regulatory Authorities in the ROW, and (b) copies of all meeting minutes and summaries of all meetings, conferences, and discussions held by Licensee or its Affiliates or sublicensees with the Regulatory Authorities in the ROW, including copies of all contact reports produced by Licensee or its Affiliates or sublicensees, in each case ((a) and (b)) within [***] following the end of each Calendar Quarter (which Licensee may provide to Pfizer through upload to a mutually acceptable data room). If such written or electronic correspondence received from any such Regulatory Authority relates to the withdrawal, suspension, or revocation of any Regulatory Approval for a Product, the prohibition or suspension of the supply of a TL1A Antibody or Product, or the initiation of any investigation, review, or inquiry by such Regulatory Authority concerning the safety of a TL1A Antibody or Product, Licensee shall notify Pfizer and provide Pfizer with copies of such written or electronic correspondence as soon as practicable, but not later than [***] after receipt of such correspondence.

5.4.5 ROW Meeting Rights. Licensee shall provide Pfizer with prior written notice of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the ROW relating to a Product, within [***] after Licensee or its Affiliate or sublicensee first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give Pfizer a reasonable opportunity to attend such meeting, conference, or discussion). [***]

5.4.6 Transfer of Regulatory Approvals in the ROW. As soon as practicable and in any event within [***] following receipt of Regulatory Approval for a Product in a country in the ROW, Licensee shall execute and provide to Pfizer all documents (in a form reasonably acceptable to Pfizer) required to transfer such Regulatory Approval to Pfizer, *provided* that if the provision of any such documents is delayed by a Regulatory Authority for reasons outside of Licensee's reasonable control, then such period will be extended for the period of delay by such Regulatory Authority. Licensee shall provide Pfizer with the status of the progress of each such Regulatory Approval transfer [***]. Licensee shall also provide a copy of each certificate of registration of the transfer of each such Regulatory Approval to Pfizer promptly after receiving such certificate from the respective Regulatory Authority. Licensee shall use Commercially Reasonable Efforts to keep the transition of Regulatory Approvals for Products in the ROW as short as possible. Pfizer shall use Commercially Reasonable Efforts to assist, or to cause its Affiliates to assist, Licensee and its Affiliates in the transfer of Regulatory Approvals for Products in the ROW to Pfizer, including by providing Licensee and its Affiliates with any information reasonably requested by Licensee and necessary for the transfer of such Regulatory Approvals or requested by any Regulatory Authority and, in each case, reasonably available to Pfizer or its Affiliates. Following the transfer of a Regulatory Approval for a Product in a country in the ROW to Pfizer, Pfizer shall bear all responsibility and expense for maintaining such Regulatory Approval.

5.4.7 Priority Review Voucher. If Licensee elects to transfer to a Third Party or otherwise monetize a Priority Review Voucher, all proceeds thereof shall be allocated to Licensee.

5.5 Progress Reporting.

5.5.1 [*]**

5.5.2 Semi-Annual Reports. During the First Reporting Window, [***].

5.5.3 Annual Reports. For each Reporting Category, after the end of the applicable First Reporting Window, Licensee's reporting obligations will be limited as follows: [***].

5.5.4 Conclusion of Reports. Notwithstanding the foregoing, Licensee's reporting obligations to Pfizer under Section 5.5.1 or 5.5.3 with respect to any and all Products described therein shall end on [***].

5.5.5 Cooperation. Licensee shall promptly respond to Pfizer's reasonable inquiries regarding the Development activities related to the TL1A Antibody and Products, and regarding clinical recruitment progress, occurred adverse events, and the status of any applications for Regulatory Approvals related to the TL1A Antibody and Products in Development by Licensee.

5.6 Permitted Contractors. Licensee may subcontract with Permitted Contractors to handle certain clinical Development or Manufacture activities in the Territory and Commercialization activities in the U.S. and Japan, in Licensee's reasonable discretion, consistent with the then-current Development Plan. As between the Parties, all costs of Permitted Contractors will be borne solely by Licensee.

5.7 Development Plan. Licensee's plan for conducting Development activities with respect to the TL1A Antibody and Products is set forth in the development plan set forth in Schedule 5.7, as amended by Licensee pursuant to this Section 5.7 (the "**Development Plan**"). For clarity, the Development Plan shall not cover the Ongoing Clinical Trials, and the Development Plan is provided for informational purposes only and is not intended to expand or diminish the scope of Licensee's diligence obligations in Section 5.3. [***]

5.8 Safety Reporting. The safety units from each of the Parties shall agree upon a pharmacovigilance agreement (the “**Pharmacovigilance Agreement**”) for exchanging adverse event and other safety information relating to the TL1A Antibody and Products prior to both Parties’ initiation of any clinical or marketing activity implicating pharmacovigilance obligations for the TL1A Antibody and Products in the Territory. Such Pharmacovigilance Agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Laws, including any local regulatory requirements as a Regulatory Approval holder.

5.9 Ongoing Clinical Trials.

5.9.1 General. From and after the Effective Date, Pfizer shall remain as sponsor of, and have sole decision making authority and responsibility for directing the activities and conduct of, the Clinical Trial of the Product that is ongoing as of the Effective Date and set forth on Schedule 1.114 [***].

(a) Within [***] after the end of each Calendar Quarter, Pfizer shall deliver to Licensee an invoice setting forth the Ongoing Clinical Trial Costs reimbursable by Licensee pursuant to this Section 5.9.2, together with [***].

5.10 Compliance. Licensee shall, and shall cause its Affiliates, to comply with all Applicable Laws with respect to the Development and Manufacture of the Products.

6. COMMERCIALIZATION.

6.1 General.

6.1.1 U.S. and Japan. As between the Parties, Licensee shall have sole responsibility for [***] and the sole authority over and control of, the Commercialization of the TL1A Antibody and Products in the Field in the U.S. and Japan. Licensee shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Products in the U.S. and Japan and to perform or cause to be performed all related services. Licensee shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Products in the U.S. and Japan.

6.1.2 ROW. As between the Parties, Pfizer shall have sole responsibility for [***] and the sole authority over and control of, the Commercialization of the TL1A Antibody and Products in the Field in the ROW. Pfizer shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Products in the ROW and to perform or cause to be performed all related services. Pfizer shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Products in the ROW.

6.2 Diligence.

6.2.1 Licensee. Licensee shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize [***].

6.2.2 Pfizer. Pfizer shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize [***].

6.3 [*]**

6.4 Territory Integrity.

6.4.1 Pfizer hereby covenants and agrees that during the Term it shall not (and shall cause its Affiliates not to), either itself or through a Third Party, Commercialize any Products for use in the Field in the United States or Japan. Without limiting the generality of the foregoing, Pfizer shall not (a) engage in any advertising activities relating to Products for use in the Field directed primarily to customers located in the United States or Japan or (b) actively or intentionally solicit orders from any prospective purchaser of a Product for use in the Field located in the United States or Japan. To the extent permitted by Applicable Law, if Pfizer receives any order from a prospective purchaser for a Product in the Field located in the United States or Japan, Pfizer shall promptly refer that order to Licensee and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Product under such order. If Pfizer should reasonably know that its customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of any Product inside the United States in the Field, then Pfizer shall (i) within [***] of becoming aware of such activities, notify Licensee regarding such activities and provide all information reasonably available to Pfizer that Licensee may reasonably request concerning such activities and (ii) use Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution inside the United States in the Field, unless otherwise agreed in writing by the Parties.

6.4.2 Licensee hereby covenants and agrees that during the Term it shall not (and shall cause its Affiliates not to), either itself or through a Third Party, Commercialize any Products for use in the Field in the ROW. Without limiting the generality of the foregoing, with respect to countries within the ROW, Licensee shall not (a) engage in any advertising activities relating to Products for use in the Field directed primarily to customers located in such countries within the ROW or (b) actively or intentionally solicit orders from any prospective purchaser of a Product for use in the Field located in such countries within the ROW. To the extent permitted by Applicable Laws, if Licensee receives any order from a prospective purchaser for a Product in the Field located in a country inside of the ROW, Licensee shall promptly refer that order to Pfizer and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Product under such order. If Licensee should reasonably know that its customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of any Product inside the ROW in the Field, then Licensee shall (i) within [***] of becoming aware of such activities, notify Pfizer regarding such activities and provide all information reasonably available to Licensee that Pfizer may reasonably request concerning such activities and (ii) use Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution inside the ROW in the Field, unless otherwise agreed in writing by the Parties.

6.5 [***]

6.6 Compliance. Each Party shall, and shall cause its Affiliates, to comply with all Applicable Laws, Anti-Corruption Laws, and Healthcare Laws with respect to the Commercialization of the Products.

7. PAYMENT TERMS.

7.1 Inventory. The inventory set forth on Schedule 7.1 shall be transferred to Licensee at no additional cost to Licensee as soon as reasonably practicable, and in any event within [***].

7.2 Royalty Payments.

7.2.1 Licensee. Subject to Section 7.5, Licensee shall pay to Pfizer non-refundable, non-creditable royalties in the amount of the flat royalty rate (set forth below) (“**Licensee Royalty Rate**”) on the aggregate Net Sales resulting from the sale of Products, on a Product-by-Product basis, in the U.S. and Japan, during each Licensee Year (collectively, “**Licensee Royalties**”).

U.S. AND JAPAN NET SALES	LICENSEE ROYALTY RATE
[***]	[***]

Within [***] following the expiration of each Licensee Quarter after the date of the First Commercial Sale in the U.S., Licensee will provide Pfizer, via email notification to the Alliance Manager, [***] and to a finance contact provided by Pfizer, a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Product in the U.S. and Japan and all Licensee Royalties payable to Pfizer for the applicable Licensee Quarter, following which Pfizer shall provide a written acknowledgement (which may be via email notification) of Licensee’s report and changes to Pfizer’s bank account information, if any. Licensee shall pay to Pfizer the Licensee Royalties within [***] following receipt of Pfizer’s written acknowledgement. Licensee Royalties will be payable on a Product-by-Product basis during the Royalty Term for such Product until the expiration of the Royalty Term for such Product in the U.S. and Japan. For purposes hereof, Net Sales during the Royalty Term for each Product in the U.S. and Japan include sales of such Products that occur after the expiration of the Royalty Term or termination of this Agreement where the Manufacture, use or other Exploitation of such Products was Covered by a Valid Claim of a Licensed Patent Right during the Royalty Term.

7.2.2 Pfizer. Subject to Section 7.5, Pfizer shall pay to Licensee non-refundable, non-creditable royalties in the amount of the flat royalty rate (set forth below) (“**Pfizer Royalty Rate**”) on the aggregate Net Sales resulting from the sale of Products, on a Product-by-Product basis, in the ROW during each Pfizer Year (collectively, “**Pfizer Royalties**”).

ROW NET SALES	PFIZER ROYALTY RATE
[***]	[***]

Pfizer shall pay to Licensee the applicable Pfizer Royalties within [***] following the expiration of each Pfizer Quarter after the date of the First Commercial Sale in the ROW. All Pfizer Royalty payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Product in the ROW and all Pfizer Royalties payable to Licensee for the applicable Pfizer Quarter (including any foreign exchange rates employed). Pfizer Royalties will be payable on a Product-by-Product and country-by-country basis during the Royalty Term for such Product in each country until the expiration of the Royalty Term for such Product in such country in the ROW. For purposes hereof, Net Sales during the Royalty Term for each Product in the ROW include sales of such Products that occur after the expiration of the Royalty Term or termination of this Agreement where the Manufacture, use or other Exploitation of such Products was Covered by a Valid Claim of a Licensed Patent Right during the Royalty Term.

7.3 **Royalty Deduction.**

7.3.1 Expiration of Valid Claims and Regulatory Exclusivity. If, on a country-by-country and Product-by-Product basis, the Royalty Term for such Product in such country is only being calculated under [***] then the Licensee Royalty Rate or Pfizer Royalty Rate used to calculate the Licensee Royalties or Pfizer Royalties, as applicable, with respect to such Product in such country shall be reduced [***]. If, on a country-by-country and Product-by-Product basis, the Royalty Term for such Product in such country is only being calculated under [***], then the Licensee Royalty Rate or Pfizer Royalty Rate used to calculate the Licensee Royalties or Pfizer Royalties, as applicable, with respect to such Product in such country shall be reduced by [***].

7.3.2 Third Party Licenses.

(a) Licensee, its Affiliates and sublicensees shall have the first right to obtain a license under any Third Party Patent Rights [***] for the Exploitation of any TL1A Antibody in any Product in the Field in the Territory (each such license, a “**Licensee Third Party License**”). Licensee, or its applicable Affiliate or sublicensee, shall pay all amounts due under any such Licensee Third Party License; *provided*, that Licensee shall be entitled to reduce the Licensee Royalties due to Pfizer upon Net Sales of a Product by up to [***].

(b) If Licensee does not, with respect to its first right under Section 7.3.2(a), obtain a license under any Third Party Patent Rights that is necessary or reasonably useful for the Commercialization of any TL1A Antibody in any Product in the Field in the ROW (“**Pfizer Third Party License**”), then Pfizer, its Affiliates and sublicensees shall have the right to obtain such Pfizer Third Party License. Pfizer, or its applicable Affiliate or sublicensee, shall pay all amounts due under Pfizer Third Party Licenses; *provided*, that Pfizer shall be entitled to reduce the Pfizer Royalties due to Licensee upon Net Sales of a Product by up to [***].

7.3.3 Biosimilar Competition. If, at any time during the Royalty Term, Biosimilar Competition exists in a given country with respect to a Reference Product, then the Pfizer Royalty Rate and Licensee Royalty Rate used to calculate royalties for such Reference Product in such country shall be reduced by [***] for so long as such Biosimilar Competition exists.

7.3.4 Maximum Deductions. Notwithstanding anything in Sections 7.3.1, 7.3.2, or 7.3.3 to the contrary, under no circumstances shall the reductions set forth in this Section 7.3 cause (a) the total Licensee Royalties payable to Pfizer in any Licensee Quarter or Pfizer Royalties payable to Licensee in any Pfizer Quarter to be reduced by more than [***] of the amount that would otherwise be due without giving effect to this Section 7.3, or (b) the Licensee Royalty Rate or Pfizer Royalty Rate used to calculate Licensee Royalties in any Licensee Quarter or Pfizer Royalties in any Pfizer Quarter to be reduced by more than [***] of the rates set forth in Section 7.2. Notwithstanding the foregoing, [***].

7.4 Blended Royalty. Licensee acknowledges that (a) the Licensed Know-How and the documentation and materials transferred to Licensee pursuant to Schedule 4 is proprietary and valuable and that, without the Licensed Know-How and such documentation and materials Licensee would not be able to Develop, obtain and maintain Regulatory Approvals for, Manufacture or Commercialize the TL1A Antibody and Products, (b) access to Licensed Know-How and such documentation and materials has provided Licensee with a competitive advantage in the marketplace beyond the exclusivity afforded by the Licensed Patent Rights and any Regulatory Exclusivity and (c) Licensee Royalties are, in part, intended to compensate Pfizer for such exclusivity and such competitive advantage. The Parties agree that the Licensee Royalty Rate set forth in Section 7.2.1 reflects an efficient and reasonable blended allocation of the value provided by Pfizer to Licensee.

7.5 [***]

7.6 **Other Payments.** Licensee shall pay to Pfizer any other amounts due under this Agreement within [***] following receipt of an undisputed invoice.

7.7 Late Payments. Any undisputed amount required to be paid by a Party hereunder which is not paid on the date due shall bear simple interest thereafter accrued on the sum due to until the date of payment, to the extent permitted by law, at [***] over the prime rate effective for the date such payment was due, as reported by [***]. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent.

7.8 Currency. All amounts payable and calculations under this Agreement shall be in United States dollars. Notwithstanding anything to the contrary in this Agreement, conversion of sales recorded in local currencies shall be translated into United States dollars in a manner consistent with Pfizer's normal practices used to prepare its audited financial statements for external reporting purposes, *provided* that such practices use a widely accepted source of published exchange rates.

7.9 Method of Payment. All payments from one Party to the other Party shall be made by wire transfer via immediately available funds in U.S. dollars to credit the bank account as designated by such Party in writing to the other Party at least [***] before payment is due. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

7.10 Taxes.

7.10.1 General.

(a) Notwithstanding anything to the contrary in Section 7.10, each Party shall solely bear and pay all taxes imposed on such Party's net income or gain (in each case, however denominated) arising directly or indirectly from the activities of the Parties under this Agreement. Each Party shall comply with Applicable Laws and regulations regarding filing and reporting for income tax purposes.

(b) Subject to Section 7.10.1(a), each Party shall bear and pay [***] of any transfer, stamp or similar taxes or obligations ("**Transfer Tax**") imposed on amounts payable by the paying Party to the receiving Party in connection with this Agreement. Each Party shall cooperate with the other Party to file any tax returns (as required to be filed under Applicable Law) with respect to such Transfer Taxes.

(c) It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax (“VAT”), which shall be added thereon as applicable. In the event any payments made by a Party pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, such Party (and its representatives) shall [***] To the extent that a Party is required to deduct and withhold taxes on any payments under this Agreement, such Party shall [***].

7.10.2 Tax Actions. Notwithstanding anything in this Agreement to the contrary, if as a result of any assignment or sublicense by the paying Party of its rights or obligations under this Agreement, any change in the paying Party’s tax residency, any change in the entity that originates the payment, or any failure on the part of the paying Party to comply with Applicable Laws (other than any failure resulting from reliance on any certification or other information provided by the receiving Party with respect to the amount of withholding tax required to be withheld or deducted) with respect to withholding taxes (including filing or record retention requirements) (a “**Tax Action**”) leads to the imposition of withholding tax liability or VAT on the other Party that would not have been imposed in the absence of a Tax Action or in an increase in such liability above the liability that would have been imposed in the absence of such Tax Action, then (i) the sum payable by the Party that caused the Tax Action (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no Tax Action occurred and (ii) the sum payable by the Party that caused a Tax Action (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with Applicable Law. For the avoidance of doubt, a Party shall only be liable for increased payments pursuant to this Section 7.10.2 to the extent such Party engaged in a Tax Action that created or increased a withholding tax or VAT on the other Party.

7.10.3 Tax Credit. If a Party makes a payment in accordance with Section 7.10.2 (a “**Tax Payment**”) and (a) a credit against, relief or remission for, or repayment of any tax (“**Tax Credit**”) is attributable to that Tax Payment and (b) the receiving Party determines in good faith that it has obtained and utilized that Tax Credit on an affiliated group basis, the receiving Party shall pay to the paying Party an amount equal to such Tax Credit, net of all out-of-pocket expenses (including taxes) of such receiving Party and without interest (other than interest paid by the relevant taxing authority with respect to such Tax Credit). Notwithstanding anything else in this Section 7.10.3, in no event will the receiving Party be required to pay any amount to the paying Party pursuant to this Section 7.10.3, the payment of which would place the receiving Party in a less favorable net after-tax position than the receiving Party would have been in if the tax giving rise to such Tax Credit had not been deducted, withheld or otherwise imposed and the applicable Tax Payment had never been paid. This Section 7.10.3 shall not be construed to require the receiving Party to make available its tax returns (or any other information relating to its taxes that it deems confidential) to the paying Party or any other Person. The receiving Party shall use its commercially reasonable efforts to obtain and utilize that Tax Credit on an affiliated group basis.

7.10.4 Cooperation. The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-9 or an IRS Form W-8BEN-E, reasonably requested by the other Party in connection with any payment made under this Agreement.

7.10.5 [*]**

8. RECORDS; AUDIT RIGHTS.

8.1 Relevant Records. Each Party shall, and shall cause its Affiliates to, maintain complete and accurate patent prosecution and maintenance records and financial books and records pertaining to sale of the Products by such Party, its Affiliates or sublicensees, including any and all calculations of the applicable amounts payable hereunder (collectively, “**Relevant Records**”). Each Party shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) [***] from the creation of such records.

8.2 Audit Request. Each Party shall have the right during the Term and for [***] thereafter to engage, [***], an independent public accounting firm of nationally recognized standing reasonably acceptable to the other Party and subject to confidentiality restrictions no less stringent than those set forth in Section 11, to examine the Relevant Records from time-to-time as may be necessary to verify compliance with the terms of this Agreement. Such examinations may not (a) be conducted for any Pfizer Quarter or Licensee Quarter, as applicable, more than [***] after the end of such Pfizer Quarter or Licensee Quarter, as applicable, (b) be conducted more than once in any [***] period or (c) be repeated for the records for any Pfizer Quarter or Licensee Quarter, as applicable. Such audit shall be requested in writing at least [***] in advance and shall be conducted during the audited Party's normal business hours and otherwise in a manner that minimizes any interference to the audited Party's business operations. The accounting firm shall disclose only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. [***]

8.3 Audit Fees and Expenses. The auditing Party shall bear [***] it may incur in connection with any such audit of the Relevant Records; *provided, however*, that in the event that an audit reveals an underpayment by the other Party of more than [***] as to the period subject to the audit, the other Party shall reimburse the auditing Party for any reasonable and documented out-of-pocket costs and expenses of the audit within [***] after receiving invoices thereof, and notwithstanding the provisions of Section 8.2, the auditing Party shall have the right to have the accounting firm examine the Relevant Records of the other Party up to [***] for [***] period following the audit revealing such underpayment.

8.4 Payment of Deficiency. If any audit establishes that (a) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 7.7 or (b) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((a) or (b)), within [***] after the date on which such audit is completed by the auditing Party.

9. INTELLECTUAL PROPERTY RIGHTS.

9.1 Pre-existing IP. Subject only to the rights expressly granted to Licensee under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to or independent of this Agreement.

9.2 Ownership of Intellectual Property.

9.2.1 Joint Developed IP. Except as otherwise set forth in this Agreement, Pfizer and Licensee shall jointly own any Joint Developed IP. Subject to the Parties' other rights and obligations under this Agreement, each Party shall be free to Exploit and assign, either itself or through the grant of licenses to Third Parties, Joint Developed IP throughout the world without restriction, without the need to obtain further consent from or provide notice to the other Party, and without any duty to account or otherwise make any payment of any compensation to the other Party. During the Term, each Party shall have an obligation to fully disclose to the other Party all Joint Developed IP in writing promptly within [***] after it becomes known to such Party, and in any event, prior to making any first patent filing in respect of such Joint Developed IP. Inventorship shall be determined according to U.S. patent law. Within [***] after receipt of written disclosure of any Joint Developed IP, the Parties shall meet to evaluate and discuss whether the disclosure is complete and sufficiently discloses an invention and agree upon the exclusion or inclusion of Confidential Information. Both Parties agree to give due consideration to the timely and reasonable recommendation of the other Party with respect to their Confidential Information and the patent strategy of the Joint Developed IP.

9.2.2 Ownership of Licensee Developed IP. Except as otherwise set forth in this Agreement, Licensee shall own all right, title and interest in and to any Licensee Developed IP.

9.2.3 Ownership of Pfizer Developed IP. Except as otherwise set forth in this Agreement, Pfizer shall own all right, title and interest in and to any Pfizer Developed IP.

9.2.4 Implementation. Each Party shall execute and deliver all documents and instruments reasonably requested by the other Party to evidence, file for, perfect or enforce its rights hereunder. Each Party shall make its relevant personnel (and their assignments and signatures on such documents and instruments) reasonably available to the other Party for assistance in accordance with this Section at no charge.

9.3 Patent Prosecution.

9.3.1 Pfizer Patent Prosecution and Maintenance. Pfizer will be responsible for filing, prosecuting (including in connection with any reexaminations, revocation proceedings, *inter partes* reviews, oppositions and the like) and maintaining the Licensed Patent Rights, Pfizer Developed IP, and Joint Developed IP in the Territory [***]. For clarity, it is agreed that Pfizer may use internal patent counsel, filing clerks, and paralegals employed by Pfizer, for coordinating worldwide filings of such Patent Rights, for prosecution before the European and Japanese patent offices, and for directly instructing U.S. outside counsel and ex-U.S. patent agents, including by providing draft applications and responses, and that Pfizer may employ its preferred patent counsel or agents including those Pfizer refers to as members of the Pfizer Legal Alliance to conduct such activities as required for U.S. and ex-U.S. prosecution. During the Term, Pfizer will provide notice to Licensee of any substitution of such counsel, foreign agents or annuity service providers within [***] after such substitution. Before each submission is filed, Pfizer will provide Licensee a reasonable opportunity to review and comment on proposed, substantive submissions to any patent office and reasonably consider any comments provided by Licensee's patent counsel. Pfizer will keep Licensee reasonably informed of the status of the Licensed Patent Rights, Pfizer Developed IP and Joint Developed IP by timely providing Licensee copies of significant communications relating to such Patent Rights that are received from any patent office or patent counsel of record or foreign associate of which Pfizer receives. Pfizer will provide Licensee with a written update of the Licensed Patent Rights listed on Schedule 1.87 which it prepares, files, prosecutes or maintains once every [***] or upon reasonable request by Licensee.

9.3.2 Licensee Patent Prosecution and Maintenance. Licensee will be responsible for filing, prosecuting (including in connection with any reexaminations, revocation proceedings, *inter partes* reviews, oppositions and the like) and maintaining the Licensee Developed IP in the Territory and in Licensee's name [***]. If Licensee elects not to file a patent application for Licensee Developed IP in a jurisdiction in the ROW or elects to cease the prosecution or maintenance of any Licensee Developed IP in a jurisdiction in the ROW, Licensee will provide Pfizer with written notice [***] before any action is required, upon the decision to not file or continue the prosecution of such patent application or maintenance of such patent. In such event, Licensee will permit Pfizer to file or continue prosecution or maintenance of any such Patent Right within the Licensee Developed IP in such jurisdiction, [***]. During the Term, Licensee will provide notice to Pfizer of any substitution of such counsel, foreign agents or annuity service providers within [***] after such substitution. Before each submission is filed, Licensee will provide Pfizer a reasonable opportunity to review and comment on proposed, substantive submissions to any patent office and reasonably consider any comments provided by Pfizer's patent counsel. Licensee will keep Pfizer reasonably informed of the status of the Licensee Developed IP by timely providing Pfizer copies of significant communications relating to such Licensee Developed IP that are received from any patent office or patent counsel of record or foreign associate of which Licensee receives. Licensee will provide Pfizer with a written update of the Licensee Developed IP which it prepares, files, prosecutes or maintains once every [***] or upon reasonable request by Pfizer.

9.3.3 Cooperation. The Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of the Licensed Patent Rights and Joint Developed IP in the Territory under this Agreement. Cooperation shall include (a) executing all papers and instruments or requiring its employees or contractors to execute such papers to effectuate the ownership and rights, including Patent Right extensions, supplementary protection certificates and the like, under this Agreement; (b) assisting in any license registration processes applicable to a particular Governmental Authority; and (c) promptly informing the other Party of any matters coming to such Party's attention that may materially affect the preparation, filing, prosecution, or maintenance of any such Licensed Patent Rights and Joint Developed IP in the Territory.

9.3.4 Patent Term Extensions. Licensee shall provide Pfizer with notice of each marketing application and approval within [***] of such application and approval. Pfizer shall have the first right with respect to making decisions regarding patent term extensions, including supplementary protection certificates, patent term linkages and any other extensions that are now or in the future become available, wherever applicable (each, a "**Patent Term Extension**"), for Licensed Patent Rights in any country or other jurisdiction in connection with the Product. Prior to selecting any such Patent Rights for a Patent Term Extension in the United States and Japan, Pfizer shall notify Licensee of any such selection and, at Licensee's request, discuss in good faith any issues or comments Licensee may have with respect to the selection of such Patent Rights, and Pfizer shall take into consideration Licensee's reasonable comments. Pfizer shall have the responsibility of applying for any Patent Term Extension with respect to such Patent Rights and the Products in the Territory. Pfizer shall consult with Licensee and keep Licensee fully informed of its efforts to obtain such Patent Term Extension in the United States and Japan. As reasonably requested by Pfizer in writing, Licensee shall cooperate, [***], in obtaining such Patent Term Extension in the United States and Japan. Pfizer agrees to execute and deliver such further authorizations and instruments in advance of submission to provide Licensee with reasonable comment rights and Pfizer agrees to take into consideration such further actions as may be requested by Pfizer to implement the foregoing. If Pfizer does not exercise its rights to file Patent Term Extensions on any Licensed Patent Right in the United States and Japan, Licensee shall have the right, on a country-by-country basis to file a Patent Term Extension for such Licensed Patent Rights [***]; *provided, however*, that Licensee shall not have such right in a country if such filing by Licensee would preclude Pfizer from filing a Patent Term Extension for another Patent Right of Pfizer's choosing in such country.

9.3.5 Failure to Prosecute or Maintain Licensed Patent Rights, Pfizer Developed IP, or Joint Developed IP. Unless otherwise agreed in writing by Licensee, Pfizer shall file, prosecute (including in connection with any reexaminations, revocation proceedings, *inter partes* reviews, oppositions and the like) and maintain each of the Licensed Patent Rights for at least [***] after the Effective Date. After the [***] anniversary of the Effective Date with respect to Licensed Patent Rights or at any time with respect to Pfizer Developed IP or Joint Developed IP, in the event Pfizer elects to forego filing, prosecution or maintenance of the Licensed Patent Rights, Pfizer Developed IP or Joint Developed IP in the United States or Japan, Pfizer shall notify Licensee of such election at least [***] prior to any filing or payment due date, or any other due date that requires action (“**Pfizer Election Notice**”). Upon receipt of a Pfizer Election Notice, Licensee shall be entitled, upon written notice to Pfizer, at its sole discretion [***], to file or to continue the prosecution or maintenance of such Patent Right in such country in Licensee’s name using counsel of its own choice [***]. As of the date Pfizer provides Licensee such Pfizer Election Notice, Licensee shall have the right, at its discretion, to either (a) terminate the applicable license to such specific Licensed Patent Right or Pfizer Developed IP or (b) convert the license granted in Section 2.1.1 under such Patent Right to a non-exclusive and non-sublicensable license. In each case, Pfizer shall promptly take all necessary steps to allow Licensee to take over prosecution and maintenance and will have no further rights in respect of the filing, maintenance or enforcement of such Patent Right.

9.3.6 Failure to Prosecute or Maintain Licensee Developed IP. In the event that Licensee elects to forego filing, prosecution or maintenance of Licensee Developed IP in the U.S. or Japan, Licensee shall notify Pfizer of such election at least [***] prior to any filing or payment due date, or any other due date that requires action (“**Licensee Election Notice**”). Upon receipt of a Licensee Election Notice, Pfizer shall be entitled, upon written notice to Licensee, at its sole discretion [***], to file or to continue the prosecution or maintenance of such Patent Right in such country in Pfizer’s name using counsel of its own choice [***]. As of the date Licensee provides Pfizer such Licensee Election Notice, Pfizer shall have the right, at its discretion, to terminate the applicable license to such specific Licensee Developed IP. In each case, Licensee shall promptly take all necessary steps to allow Pfizer to take over prosecution and maintenance and will have no further rights in respect of the filing, maintenance or enforcement of such Patent Right.

9.4 Trademarks.

9.4.1 Determination and Ownership of Product Trademarks. Licensee shall determine, in consultation with Pfizer, and exclusively own all right, title and interest in and to the Trademarks for Products Commercialized in the United States and Japan (the “**Licensee Product Trademarks**”), *provided* that if a Trademark cannot be registered or used under Applicable Law (for regulatory, trademark law or other legal reasons), such Trademark will not be used and an alternate Trademark will be selected by Licensee in consultation with Pfizer. Pfizer shall determine and select, in its sole discretion, the Trademarks for Products Commercialized in the ROW (the “**Pfizer Product Trademarks**”), including that Pfizer may elect, in its sole discretion, to use a Trademark which is identical to a Licensee Product Trademark as a Pfizer Product Trademark, and Pfizer shall exclusively own all right, title and interest in and to the Pfizer Product Trademarks.

9.4.2 Registration, Prosecution, Maintenance, Enforcement and Defense of Product Trademarks. Licensee shall have the right, using counsel of its own choice, to conduct clearance activities (including searches), register, prosecute, maintain and enforce the Licensee Product Trademarks [***]. Pfizer shall have the right, using counsel of its own choice, to conduct clearance activities (including searches), register, prosecute, maintain and enforce the Pfizer Product Trademarks [***].

9.4.3 Corporate Names. Each Party and its Affiliates will retain all right, title and interest in and to its and their respective house marks, corporate names and corporate logos. Each Party shall not, and shall cause its Affiliates and its or their respective sublicensees not to (a) do any act in connection with this Agreement that endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the corporate names of the other Party or (b) attack, dispute or contest the validity of or ownership of the corporate names of the other Party anywhere in the world or any registrations issued or issuing with respect thereto. Each Party shall, and shall cause its Affiliates and its and their respective sublicensees to, conform (y) to the customary industry standards for the protection of the corporate names of the other Party and (z) to maintain the quality standards of the other Party with respect to the goods sold and services provided in connection with the corporate names of such other Party.

9.5 [***]

10. INFRINGEMENT; MISAPPROPRIATION.

10.1 Notification. Each Party will promptly notify the other Party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Technology in the Field and in the Territory of which it becomes aware, including (i) a Third Party application under BPCIA or licensure of a Biosimilar Product, (ii) any certification under a similar statutory or regulatory requirement in any non-United States country, claiming that any Licensed Patent Rights Covering the TL1A Antibody or any Product is invalid or that infringement will not arise from the Development, Manufacture or Commercialization of the proposed Biosimilar Product by such Third Party, or (iii) declaratory judgement action against any Licensed Patent Right in the Territory in connection with any such infringement (“**Third Party Infringement**”). Any such notice shall include a summary of available information that would support Licensee’s performance of its obligations under this Section 10.1.

10.2 Infringement Action.

10.2.1 Right of First Enforcement.

(a) Pfizer shall have the first right (but not the obligation), [***], to control enforcement of the Licensed Technology and Joint Developed IP or any continuation or divisional thereof against any actual or threatened Third Party Infringement in the ROW and in Pfizer's name [***]. Prior to commencing any such action, Pfizer shall consult with Licensee and shall give due consideration to Licensee's timely and reasonable recommendations regarding the proposed action. Pfizer shall give Licensee timely notice of any proposed settlement of any such action instituted by Pfizer and shall not, without the prior written consent of Licensee, which shall not be unreasonably withheld, conditioned or delayed, enter into any settlement that would adversely affect the validity, enforceability or scope of the Licensed Technology. Subject to Pfizer's rights set forth in Section 10.2.1(c) below, Licensee shall have the first right (but not the obligation), [***], to control enforcement of the Licensed Technology and Joint Developed IP against any Third Party Infringement in the United States and Japan. If Licensee elects to control enforcement in the United States, Pfizer shall cooperate, as reasonably requested by Licensee, in a manner consistent with this Section 10.2.1. Pfizer hereby authorizes Licensee to: (a) provide in any BLA or, in connection with the BPCIA, a list of Licensed Patent Rights and Pfizer Developed IP as required under the BPCIA; (b) exercise any rights exercisable by Licensee as an exclusive licensee under the BPCIA; and (c) exercise any rights that may be exercisable by Licensee as reference product sponsor under the BPCIA, including (1) engaging in the Patent Right resolution provisions of the BPCIA with regard to Pfizer Patent Rights Covering the TL1A Antibody or any Products; and (2) determining which Patent Rights will be the subject of an immediate patent infringement action under 42 U.S.C. § 262(l)(6) of the BPCIA; *provided* that with respect to Licensee's exercise of rights under the BPCIA, Licensee shall consult with a representative of Pfizer designated by Pfizer in writing and qualified to receive confidential information pursuant to § 262(l)(1) of the BPCIA with respect to Licensee's exercise of any rights exercisable as reference product sponsor, including providing such representative with timely copies of material correspondence relating to such matters, providing such representative the opportunity, reasonably in advance of any related Licensee action, to comment thereon and to consult with and consider in good faith the requests and suggestions of Pfizer with respect to such matters. In order to establish standing, Pfizer, upon the request of Licensee, agrees to timely commence or to join any such litigation [***], and to cooperate with Licensee in such litigation [***]. Licensee shall give Pfizer timely notice of any proposed settlement of any such action instituted by Licensee and shall not, without the prior written consent of Pfizer [***], which in the case of (i), (iii) and (iv) below shall not be unreasonably withheld, conditioned or delayed, enter into any settlement that would: (i) adversely affect the validity, enforceability or scope of any of the Licensed Patent Rights, (ii) give rise to liability of Pfizer or its Affiliates, (iii) admit non-infringement of any Licensed Patent Rights, or (iv) otherwise impair Pfizer's rights in any Licensed Technology or this Agreement.

(b) If Pfizer does not, with respect to its first right of enforcement under Section 10.2.1(a), obtain agreement from the alleged infringer to desist or fails or refuses to initiate an infringement action by the earlier of (i) [***] following Pfizer's receipt of notice of the alleged infringement, or (ii) [***] before the expiration date for filing such actions, then Pfizer shall inform Licensee within earlier of (i) [***] following Pfizer's receipt of notice of the alleged infringement, or (ii) [***] before the expiration date for filing such actions that Licensee shall have the right, at its sole discretion, to control such enforcement of the Licensed Technology in the ROW at its sole expense, [***]. Licensee will then notify Pfizer within [***] whether it elects to control such enforcement of the Licensed Technology in the ROW [***].

[***]

10.2.2 Recoveries. Any recoveries resulting from an action instituted by Licensee relating to a claim of Third Party Infringement pursuant to Section 10.2.1(a) shall first be allocated [***] and any other amount [***] shall be further allocated as follows: such recoveries shall first be applied to reimburse each Party's costs and expenses incurred in connection therewith. Any remaining recoveries shall be retained by (or if received by Pfizer, paid to) Licensee; [***]. If Licensee fails to institute an action or proceeding and Pfizer exercises its right to prosecute such infringement pursuant to Section 10.2.1(b), any remaining recoveries shall be retained by Pfizer.

11. CONFIDENTIALITY [*].**

11.1 Obligations. The receiving Party will protect all Confidential Information against unauthorized disclosure to Third Parties with the same degree of care as the receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The receiving Party may only use the Confidential Information for exercising its rights and performing its obligations under this Agreement, and may only disclose the Confidential Information to [***] (collectively, "**Recipients**") who have a need to know such information for exercising its rights and performing its obligations under this Agreement, *provided* that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement. All obligations of confidentiality under this Agreement shall survive expiration or termination of this Agreement for a period of [***].

11.2.1 Disclosure Required by Law. The restrictions set forth in this Section 11 shall not apply to any Confidential Information that the receiving Party is required to disclose under Applicable Laws, the rules of any recognized stock exchange or any Order, *provided* that the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the disclosing Party an opportunity to oppose, limit or secure confidential treatment for such required disclosure and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is required to disclose under Applicable Laws or the rules of any recognized stock exchange or such Order as advised by the receiving Party's legal counsel; *provided* that before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.2.1, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the disclosing Party providing as much advanced notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. For the avoidance of doubt, Licensee shall be permitted to file this Agreement with the Securities and Exchange Commission in connection with an initial public offering of Licensee's stock or as otherwise required by Applicable Law; *provided* that Licensee shall, [***], seek such confidential treatment of confidential portions of this Agreement as may be reasonably requested by Pfizer. Notwithstanding the foregoing or anything else to the contrary in this Agreement, each Party (and each employee, representative or other agent of any Party) may disclose to any and all persons, without limitation of any kind, the tax treatment and tax structure of, and tax strategies relating to, the transactions in which such Party participates pursuant to this Agreement. For this purpose, "tax structure" is limited to any facts relevant to the United States federal income tax treatment of such transactions and does not include information relating to the specific identity of the Parties.

11.2.2 Disclosure to Assignee of Payments.

(a) In the event that Pfizer wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Licensee Royalties payable hereunder, Pfizer may disclose to a Third Party Confidential Information of Licensee reasonably relevant to such Licensee Royalties in connection with any such proposed assignment, *provided* that Pfizer shall hold such Third Parties to written obligations of confidentiality and non-use with terms and conditions at least as restrictive as those set forth in this Agreement.

(b) In the event that Licensee wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Pfizer Royalties payable hereunder, Licensee may disclose to a Third Party Confidential Information of Pfizer reasonably relevant to such Pfizer Royalties in connection with any such proposed assignment, *provided* that Licensee shall hold such Third Parties to written obligations of confidentiality and non-use with terms and conditions at least as restrictive as those set forth in this Agreement.

11.2.3 [*]**

11.2.4 Use of Residuals. The restrictions set forth in this Section 11 shall not apply to the use of Residuals in accordance with Section 2.6.

11.3 Ongoing Obligation for Confidentiality. Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except that the receiving Party (a) may retain a single copy of Confidential Information for the sole purpose of (i) ascertaining its rights and responsibilities in respect of such information and (ii) exercising its rights that expressly survive the expiration or termination of this Agreement and (b) shall not be required to destroy any computer files stored securely by the receiving Party that are created by automatic system back up.

11.4 [*]**

12. REPRESENTATIONS, WARRANTIES AND COVENANTS.

12.1 Representations, Warranties and Covenants by Each Party. Each Party represents and warrants to the other Party as of the Effective Date, and covenants that:

12.1.1 it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

12.1.2 it has full corporate power and authority to execute, deliver, and perform under the Transaction Agreements to which it will be a party, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of the Transaction Agreements to which it will be a party and the consummation of the transactions contemplated by the Transaction Agreements to which it will be a party;

12.1.3 the Transaction Agreements to which it will be a party will, at and after the Closing, constitute a valid and binding agreement enforceable against it in accordance with their terms;

12.1.4 all consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with the Transaction Agreements to which it will be a party have been obtained; and

12.1.5 the execution and delivery of the Transaction Agreements to which it will be a party and all other instruments and documents required to be executed pursuant to the Transaction Agreements to which it will be a party, and the consummation of the transactions contemplated thereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations thereunder; or (iii) violate any Applicable Law.

12.2 Representations, Warranties and Covenants by Pfizer. Pfizer represents and warrants to Licensee as of the Effective Date, and covenants that:

[***]

12.3 Representations, Warranties and Covenants by Licensee.

[***]

12.4 Representations, Warranties and Covenants Related to Anti-Corruption Laws and Healthcare Laws. Without limiting the generality of Section 12.3.2, Licensee represents, warrants and covenants to Pfizer as of the Effective Date as follows:

[***]

12.5 Representations, Warranties and Covenants Related to Global Trade Control Laws. Without limiting the generality of Section 12.3.2, Licensee represents, warrants and covenants to Pfizer as follows:

[***]

12.6 No Action Required Which Would Violate Law. In no event shall either Party be obligated under this Agreement to take any action or omit to take any action that such Party believes, in good faith, would cause such Party to violate any Applicable Law, including the Anti-Corruption Laws and Global Trade Control Laws.

12.7 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 12, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 12, ANY INFORMATION OR MATERIALS PROVIDED BY PFIZER OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

12.8 Disclaimer. Licensee hereby expressly acknowledges and agrees that Pfizer makes no representation or warranty with respect to any estimates, projections, forecasts, plans or budgets that may have been provided to Licensee. Licensee (a) specifically disclaims that it is relying upon or has relied upon any representations or warranties other than as set forth in Sections 12.1 and 12.2, that may have been made by any Person, and acknowledges and agrees that Pfizer and its Affiliates specifically disclaimed and do hereby specifically disclaim any such other representation or warranty made by any Person, (b) specifically disclaims any obligation or duty by Pfizer and its Affiliates to make any disclosures of fact not required to be disclosed pursuant to the specific representations and warranties set forth in Sections 12.1 and 12.2 and (c) is entering into the transactions contemplated hereby and acquiring the Licensed Technology in connection with the transactions contemplated hereby subject only to the specific representations and warranties of Pfizer set forth in Sections 12.1 and 12.2. Licensee hereby further acknowledges that (i) it has conducted, to its satisfaction, an independent investigation, due diligence review and verification of the Licensed Technology and (ii) it is an informed and sophisticated Person and has engaged advisors experienced in the evaluation and consummation of transactions of the type contemplated hereunder.

12.9 Other Government Approvals. Each of Licensee and Pfizer shall cooperate with the other Party and shall use reasonable efforts to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers required in connection with this Agreement, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated hereby.

13. INDEMNIFICATION

13.1 Indemnification by Licensee. From and after the Closing, Licensee agrees to indemnify, hold harmless and defend Pfizer and its Affiliates, and its and their respective officers, directors, employees, contractors, agents and successors and assigns (collectively, “**Pfizer Indemnitees**”), from and against any Losses to the extent arising or resulting from: (a) [***], (d) the negligence, recklessness or wrongful intentional acts or omissions of Licensee or its Affiliates, contractors, subcontractors or sublicensees in the exercise of their rights or performance of their obligations hereunder, (e) breach by Licensee of any representation, warranty or covenant as set forth in this Agreement or (f) breach by Licensee of the scope of the license set forth in Section 2.1. Notwithstanding the foregoing, Licensee shall not be liable and have no obligation to indemnify Pfizer to the extent such losses arise out of or result from (a) the breach by Pfizer of any representation, warranty or covenant set forth in this Agreement, or (b) the negligence, recklessness, wrongful intentional act or omission, or violation of Applicable Law by any Pfizer Indemnitee.

13.2 Indemnification by Pfizer. From and after the Closing, Pfizer agrees to indemnify, hold harmless and defend Licensee and its Affiliates, and its and their respective officers, directors, employees, agents and successors and assigns (collectively, “**Licensee Indemnitees**”), from and against any Losses to the extent arising or resulting from: (a) the negligence, recklessness or wrongful intentional acts or omissions of Pfizer or its Affiliates, contractors, subcontractors or sublicensees in the exercise of their rights or performance of their obligations hereunder, (b) [***], or (d) breach by Pfizer of any representation, warranty or covenant as set forth in this Agreement. Pfizer shall not be liable and have no obligation to indemnify Licensee to the extent such losses arise out of or result from (a) the breach by Licensee of any representation, warranty or covenant set forth in this Agreement, or (b) the negligence, recklessness, wrongful intentional act or omission, or violation of Applicable Law by any Licensee Indemnitee.

13.3 Indemnification Procedure for Third Party Claims. In connection with any claim of a Third Party for which a Pfizer Indemnitee or Licensee Indemnitee (either of the foregoing, the “**Indemnified Party**”) seeks indemnification from the other Party (the “**Indemnifying Party**”) pursuant to this Agreement, the Indemnified Party shall: (a) give the Indemnifying Party prompt written notice of the claim, the amount or the estimated amount of damages sought under such claim to the extent then ascertainable and, to the extent practicable, any other material details pertaining thereto; *provided, however*, that failure to provide such notice or to include the foregoing information shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, [***], in connection with the defense and settlement of the claim; and (c) permit the Indemnifying Party to assume control of the defense and settlement of the claim, [***]; *provided, however*, that the Indemnifying Party may not settle the claim without the Indemnified Party’s prior written consent, which shall not be unreasonably withheld, conditioned or delayed, unless such settlement (x) provides for the payment by the Indemnifying Party of money as sole relief for the claimant (other than as contemplated by the Deductible), (y) results in the full and general release of the Indemnified Party from all liabilities arising or resulting from such claim, and (z) involves no finding or admission of any violation of Applicable Law or the rights of any Person and does not have an effect on any other claims that may be made against the Indemnified Party. If the Indemnifying Party does not assume control of the defense and settlement of such claim, then the Indemnified Party shall control the defense and settlement of such claim with counsel of its selection, [***]. Either the Indemnified Party (if such claim is controlled by the Indemnifying Party) or the Indemnifying Party (if such claim is controlled by the Indemnified Party) shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection [***]. Notwithstanding the foregoing, if the Indemnifying Party assumes control of the defense and settlement of such claim, the Indemnified Party will have the right to employ separate counsel, [***], in connection with the defense and settlement of the claim if: (i) there are or may be legal defenses available to the Indemnified Party that are different from or additional to those available to the Indemnifying Party; or (ii) in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between the Indemnified Party and Indemnifying Party that would make such separate representation advisable. In the event that the Indemnified Party controls the defense and settlement of such claim, the Indemnified Party may not settle such claim without the Indemnifying Party’s prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

13.4 Indemnification Procedure for Direct Claims. In connection with any claim for indemnification that an Indemnified Party wishes to make pursuant to this Agreement that does not arise or result from a claim by a Third Party, the Indemnified Party shall give the Indemnifying Party prompt written notice of such claim, the section(s) of this Agreement that form the basis of the claim for indemnification, the amount or the estimated amount of damages sought under such claim to the extent then ascertainable and, to the extent practicable, any other material details pertaining thereto; *provided, however*, that failure to provide such notice or to include the foregoing information shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure. Upon receipt of any such notice, the Indemnified Party and the Indemnifying Party shall use commercially reasonable efforts to cooperate and arrive at a mutually acceptable resolution of such claim within [***] of the Indemnified Party's receipt of such notice. If a mutually acceptable resolution cannot be reached between the Indemnified Party and the Indemnifying Party within such [***] period, the Indemnified Party shall be free to seek enforcement of its rights to indemnification under this Agreement with respect to such claim.

14. LIMITATION OF LIABILITY.

14.1 Damages Waiver. EXCEPT FOR [***], NEITHER PARTY SHALL BE LIABLE TO ANY PERSON HEREUNDER FOR ANY SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, OR ANY DAMAGES THAT ARE SPECULATIVE OR NOT REASONABLY FORESEEABLE AS A PROXIMATE RESULT OF THE BREACH BY A PARTY OF ANY OF ITS REPRESENTATIONS, WARRANTIES, COVENANTS OR AGREEMENTS UNDER THIS AGREEMENT, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

14.2 [*]**

14.3 [*]**

14.4 Survival. The representations and warranties contained in this Agreement shall survive the Closing until the [***] of the Effective Date, except that (a) the representations and warranties contained in Section 12.1 shall survive the Closing until [***] after expiration of the relevant statute of limitations period, and (b) the representations and warranties contained in Section 12.2.4 shall survive the Closing until the [***] of the Effective Date, and, in each case, all rights to indemnification hereunder for any breach of or inaccuracy in any representation or warranty shall terminate and expire on, and no action or proceedings seeking damages or other relief for breach of any representation or warranty or for misrepresentation or inaccuracy shall be commenced after, such date. All covenants and agreements of the Parties requiring performance in full prior to the Effective Date shall survive until the Effective Date and all other covenants and agreements contained herein shall survive until the expiration of the relevant statute of limitations period, and, in each case, all rights to indemnification hereunder for any breach of any covenant or agreement shall terminate and expire on, and no action or proceedings seeking damages or other relief for breach of any covenant or agreement shall be commenced after, such date. In the event that notice of any claim for indemnification under Section 13 has been given pursuant to Section 13.3 or Section 13.4, as the case may be, within the applicable survival period, the representations, warranties, covenants or agreements that are the subject of such indemnification claim (and the right to pursue such claim) shall survive with respect to such claim until such time as such claim is finally resolved.

14.5 Exclusive Remedy. Except for any claim for Fraud, gross negligence or willful misconduct, the provisions of Section 13 and this Section 14 shall be the exclusive monetary remedy of the Parties for any matter subject to indemnification pursuant to Section 13, except (a) as set forth in Section 18.4 and (b) to the extent the procedures of Section 2.1.5 would fully mitigate Losses with respect to a breach of any representation or warranty in this Agreement, the procedures of Section 2.1.5 will be the sole and exclusive remedy of the Licensee Indemnitees for any such breach.

14.6 Insurance Recovery. Notwithstanding the foregoing, the indemnifiable Losses shall be net of (a) the amount of any insurance proceeds actually received by the Indemnified Party (offset by any increase in premium resulting therefrom and after deducting therefrom the full amount of the out-of-pocket fees, costs and expenses incurred by it in procuring such recovery and any taxes payable or expected to be payable thereon), and each Indemnified Party agrees to file claims under each applicable insurance policy and to use commercially reasonable efforts to pursue all such insurance claims (but, shall not include an obligation to commence litigation), (b) any indemnity or contribution amounts actually recovered by such Indemnified Party from a Third Party in respect of such indemnifiable Losses (after deducting therefrom the full amount of the out-of-pocket fees, costs and expenses incurred by it in procuring such recovery and any taxes payable or expected to be payable thereon), and (c) the amount of any actual reduction in net taxes as a result of such indemnifiable Losses, solely for the taxable year of the incurrence, accrual or payment of such indemnifiable Losses (treating any such benefit as the last item of deduction for the applicable tax year).

14.7 No Set-Off. Notwithstanding anything to the contrary, neither Party shall set off any indemnifiable Losses against the Licensee Royalties or Pfizer Royalties, as applicable, that would otherwise be payable to the other Party pursuant to Section 7.

15. TERM; TERMINATION.

15.1 Term. The term of this Agreement (“**Term**”) shall commence as of the Effective Date and shall expire, on a Product-by-Product and country-by-country basis, on the expiration of the applicable Royalty Term, unless earlier terminated, as provided in this Section 15. Upon expiration of the Term for any Product, the licenses granted to Licensee under this Agreement shall become fully paid-up, royalty-free, transferable, perpetual and irrevocable, with the right to grant sublicenses, through multiple tiers, with respect to such Product in the Field in the Territory.

15.2 Termination for Cause. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in its entirety in the event the other Party materially breaches any of its obligations hereunder and fails to cure such breach within [***] of receiving notice thereof; *provided, however*, if such breach is capable of being cured, but cannot be cured within such [***] period, and breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [***]; and *provided, further*, that in the event that any such material breach by the breaching Party is limited to one or more (but not all) Products or countries, then the non-breaching Party shall have right to terminate solely with respect to all such Products or countries, as applicable. Any termination by a Party under this Section 15.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the breaching Party.

15.3 Termination for Convenience. At any time, Licensee shall have the right to terminate [***].

15.4 [*]**

15.5.1 Termination in its Entirety by Licensee for Cause or by Pfizer for [*].** In the event that Licensee terminates this Agreement in its entirety pursuant to Section 15.2 or if Pfizer terminates this Agreement in its entirety pursuant to Section 15.4, the following shall apply:

(a) **Rights and Obligations.** Except as otherwise provided herein, including pursuant to Section 15.6, all rights and obligations of each Party hereunder shall cease, including, for clarity, all licenses granted to Pfizer hereunder.

(b) **Licenses.** All rights and licenses granted to Licensee hereunder shall become fully paid-up, irrevocable and perpetual [***].

(c) **Transition.** During the notice period provided in Section 15.2, at Licensee's sole option, Licensee shall prepare and the Parties shall negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 15.5.1(c).

(i) **Continued Exploitation.** At Licensee's request [***], Pfizer shall continue on-going Exploitation for a mutually agreed-upon period following the termination of this Agreement, which period shall not be less than [***] unless otherwise agreed to by the Parties. For avoidance of doubt, if Licensee chooses not to continue a Clinical Trial initiated by Pfizer, [***] of winding down such Clinical Trial, including compliance with any ethical or other requirements imposed by an applicable Regulatory Authority.

(ii) **Technology Transfer.** At Licensee's request, Pfizer shall make available to Licensee all currently available records and data which exist and are Controlled by Pfizer as of the effective date of termination and are necessary or useful for Licensee to continue Commercializing and Exploiting the TL1A Antibody and Products in the Field in the Territory.

(iii) **Regulatory Matters.** At Licensee's request, Pfizer shall transfer and assign to Licensee (or its designee) all Regulatory Approvals and Regulatory Filings held by Pfizer with respect to the TL1A Antibody and Products, *provided* that if such transfer and assignment is not permitted by the applicable Regulatory Authority, Pfizer shall permit Licensee to cross-reference and rely upon such Regulatory Approvals and Regulatory Filings. Pfizer shall make available to Licensee copies of all regulatory documentation and records related to the TL1A Antibody and Products, including information contained in the regulatory and safety databases. The Parties shall cooperate to ensure the prompt transition of regulatory responsibilities for the TL1A Antibody and Products from Pfizer to Licensee [***].

(iv) **Trademarks.** Licensee shall have, and Pfizer does hereby grant to Licensee, a fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable license to use the Pfizer Product Trademarks, if any, solely for the purpose of using, Developing, Commercializing and Manufacturing the Products in the ROW. Licensee shall have a transitional license to use Pfizer's Trademarks and promotional materials solely for the purpose of using, Developing, Commercializing and Manufacturing the Products.

(v) **Inventory and Supply.** At Licensee's request, Pfizer shall transfer to Licensee (or its designee) all TL1A Antibody and Product, components and in-process inventory held by Pfizer with respect to the Manufacture of the TL1A Antibody and Products as of such date of termination, if any. At Licensee's request, if Pfizer has licensed to a CMO to Manufacture the TL1A Antibody or Products, Pfizer shall promptly assign such license to Licensee (to the extent allowed under such license), or if not, Pfizer shall continue to Manufacture or have Manufactured the Products for a period of not less than [***], including, at Licensee's request, a reasonable stock build. Licensee shall pay to Pfizer [***] of manufacturing associated with inventory and the TL1A Antibody or Product received by Licensee pursuant to this Section 15.5.1(c)(v).

(vi) **Third Party Agreements.** At Licensee's request, to the extent Pfizer is able to do so, Pfizer shall assign to Licensee (or its designee) any agreements with Third Parties with respect to the Development, Commercialization and Manufacture of the TL1A Antibody and Products. With respect to Third Party agreements that Pfizer is not able to assign to Licensee, Pfizer shall cooperate to give Licensee the benefit of such contracts for a reasonable transitional period.

15.5.2 Termination of Terminated Territory by Licensee for Cause. In the event that Licensee terminates this Agreement with respect to a Terminated Territory, as applicable, pursuant to Section 15.2 (but not in the case of any termination of this Agreement in its entirety), the following shall apply:

(a) **Rights and Obligations.** Except as otherwise provided herein, including pursuant to Section 15.6, this Agreement shall automatically be deemed to be amended to exclude the rights and obligations of Pfizer hereunder with respect to such Terminated Territory, including, for clarity, all licenses granted to Pfizer hereunder with respect to such Terminated Territory.

(b) **Licenses.** All rights and licenses granted to Licensee hereunder shall become fully paid-up, irrevocable and perpetual with respect to such Terminated Territory [***].

(c) **Transition.** During the notice period provided in Section 15.2, at Licensee's sole option, Licensee shall prepare and the Parties shall negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 15.5.2(c).

(i) **Continued Exploitation.** At Licensee's request [***], Pfizer shall continue on-going Exploitation with respect to such Terminated Territory, for a mutually agreed-upon period following the termination of this Agreement with respect to the Terminated Territory, which period shall not be less than [***] unless otherwise agreed to by the Parties. For avoidance of doubt, if Licensee chooses not to continue a Clinical Trial initiated by Pfizer, [***] of winding down such Clinical Trial, including compliance with any ethical or other requirements imposed by an applicable Regulatory Authority.

(ii) **Technology Transfer.** At Licensee's request, Pfizer shall make available to Licensee all currently available records and data which exist and are Controlled by Pfizer with respect to such Terminated Territory, as of the effective date of termination and are necessary or useful for Licensee to continue Commercializing and Exploiting the Products in such Terminated Territory.

(iii) **Regulatory Matters.** At Licensee's request, Pfizer shall transfer and assign to Licensee (or its designee) all Regulatory Approvals and Regulatory Filings held by Pfizer with respect to such Terminated Territory, *provided* that if such transfer and assignment is not permitted by the applicable Regulatory Authority, Pfizer shall permit Licensee to cross-reference and rely upon such Regulatory Approvals and Regulatory Filings. Pfizer shall make available to Licensee copies of all regulatory documentation and records related to such Terminated Territory, including information contained in the regulatory and safety databases. The Parties shall cooperate to ensure the prompt transition of regulatory responsibilities with respect to such Terminated Territory, from Pfizer to Licensee.

(iv) **Trademarks.** Licensee shall have, and Pfizer does hereby grant to Licensee, a fully paid-up, royalty-free, worldwide (except in the event that Licensee terminates this Agreement with respect to a Terminated Territory, and such Terminated Territory is in the ROW, in which case, such license shall be solely for the Terminated Territory) transferable, sublicensable, perpetual and irrevocable license to use the Pfizer Product Trademarks associated with all Products with respect to the Terminated Territory, if any, solely for the purpose of using, Developing, Commercializing and Manufacturing with respect to the Terminated Territory. Licensee shall have a transitional license to use Pfizer's Trademarks and promotional materials solely for the purpose of using, Developing, Commercializing and Manufacturing all Products with respect to the Terminated Territory.

(v) **Inventory and Supply.** At Licensee's request, Pfizer shall transfer to Licensee (or its designee) all TL1A Antibody and Product, components and in-process inventory held by Pfizer with respect to the Terminated Territory, as of such date of termination, if any. At Licensee's request, if Pfizer has licensed to a CMO to Manufacture any Products with respect to the Terminated Territory, and if Pfizer is able to do so, Pfizer shall promptly assign such license to Licensee, or if not, Pfizer shall continue to Manufacture or have Manufactured any Products with respect to the Terminated Territory, for a period of not less than [***], including, at Licensee's request, a reasonable stock build. Licensee shall pay to Pfizer [***] of manufacturing associated with inventory and the TL1A Antibody or Product received by Licensee pursuant to this Section 15.5.2(c)(v).

(vi) **Third Party Agreements.** At Licensee's request, to the extent Pfizer is able to do so, Pfizer shall assign to Licensee (or its designee) any agreements with Third Parties with respect to such Terminated Territory. With respect to Third Party agreements that Pfizer is not able to assign to Licensee, Pfizer shall cooperate to give Licensee the benefit of such contracts for a reasonable transitional period.

15.5.3 Termination in its Entirety by Pfizer for Cause; Termination in its Entirety for Convenience by Licensee. In the event that (i) Pfizer terminates this Agreement in its entirety pursuant to Section 15.2, or (ii) Licensee terminates this Agreement in its entirety pursuant to Section 15.3 the following shall apply:

(a) **Rights and Obligations.** Except as otherwise provided herein, including pursuant to Section 15.6, all rights and obligations of each Party hereunder shall cease, including, for clarity all licenses granted to Licensee hereunder.

(b) **Licenses.** Licensee hereby grants to Pfizer and its Affiliates, an exclusive, sublicensable, royalty-free, full paid-up, irrevocable, worldwide and perpetual right and license, with the right to assign and grant sublicenses, under the Licensee Developed IP, as it exists as of the effective date of termination, to Exploit the Products in the Field in the Territory.

(c) **Transition.** During the notice period provided in Section 15.2 and Section 15.3 as applicable to such termination, at Pfizer's sole option, Pfizer shall prepare and the Parties shall negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 15.5.3(c).

(i) **Continued Exploitation.** At Pfizer's request [***], Licensee shall continue on-going Exploitation for a mutually agreed-upon period following the termination of this Agreement, which period shall not be less than [***] unless otherwise agreed to by the Parties. For avoidance of doubt, if Pfizer chooses not to continue a Clinical Trial initiated by Licensee, [***] of winding down such Clinical Trial, including compliance with any ethical or other requirements imposed by an applicable Regulatory Authority.

(ii) **Technology Transfer.** At Pfizer's request, Licensee shall make available to Pfizer all currently available records and data which exist and are Controlled by Licensee as of the effective date of termination and are necessary or useful for Pfizer to continue Exploiting the TL1A Antibody and Products in the Field in the Territory.

(iii) **Regulatory Matters.** Licensee shall transfer and assign to Pfizer (or its designee) all Regulatory Approvals and Regulatory Filings held by Licensee with respect to the TL1A Antibody and Products, *provided* that if such transfer and assignment is not permitted by the applicable Regulatory Authority, Licensee shall permit Pfizer to cross-reference and rely upon such Regulatory Approvals and Regulatory Filings. Licensee shall make available to Pfizer copies of all regulatory documentation and records related to the TL1A Antibody and Products, including information contained in the regulatory and safety databases. The Parties shall cooperate to ensure the prompt transition of regulatory responsibilities for the TL1A Antibody and Products from Licensee to Pfizer.

(iv) **Trademarks.** Pfizer shall have, and Licensee does hereby grant to Pfizer, a fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable license to use the Licensee Product Trademarks solely for the purpose of using, Developing, Commercializing and Manufacturing the Products in the U.S. and Japan. Pfizer shall have a transitional license to use Licensee's Trademarks and promotional materials solely for the purpose of using, Developing, Commercializing and Manufacturing the Products.

(v) **Inventory and Supply.** At Pfizer's request, Licensee shall transfer to Pfizer (or its designee) all TL1A Antibody and Product, components and in-process inventory held by Licensee with respect to the Manufacture of the TL1A Antibody and Products as of such date of termination. At Pfizer's request, if Licensee has sublicensed to a CMO to Manufacture the TL1A Antibody or Products, Licensee shall promptly assign such sublicense to Pfizer, or if not, Licensee shall continue to Manufacture or have Manufactured the Products for a period of not less than [***], including, at Pfizer's request, a reasonable stock build. Pfizer shall pay to Licensee [***] of manufacturing associated with inventory and any TL1A Antibody or Product received by Pfizer pursuant to this Section 15.5.3(c)(v).

(vi) **Third Party Agreements.** At Pfizer's request, to the extent Licensee is able to do so, Licensee shall assign to Pfizer (or its designee) any agreements with Third Parties with respect to the Development, Commercialization and Manufacture of the TL1A Antibody and Products. With respect to Third Party agreements that Licensee is not able to assign to Pfizer, Licensee shall cooperate to give Pfizer the benefit of such contracts for a reasonable transitional period.

15.5.4 Terminated Territory by Pfizer for Cause. In the event that Pfizer terminates this Agreement with respect to a Terminated Territory, pursuant to Section 15.2 (but not in the case of any termination of this Agreement in its entirety), the following shall apply:

(a) **Rights and Obligations.** Except as otherwise provided herein, including pursuant to Section 15.6, this Agreement shall automatically be deemed to be amended to exclude the rights and obligations of Licensee hereunder with respect to such Terminated Territory, including for clarity, all licenses granted to Licensee hereunder with respect to such Terminated Territory.

(b) Licenses.

(i) All rights and licenses granted to Pfizer hereunder shall become fully paid-up, irrevocable and perpetual with respect to such Terminated Territory.

(ii) If Pfizer terminates this Agreement with respect to a Terminated Territory, Licensee hereby grants to Pfizer and its Affiliates, an exclusive, sublicensable, royalty-free, fully paid-up, irrevocable, and perpetual right and license, with the right to assign and grant sublicenses, under the Licensee Developed IP, as it exists as of the effective date of termination, to Exploit the Products in the Field in the Terminated Territory.

(c) **Transition.** During the notice period provided in Section 15.2, at Pfizer's sole option, Pfizer shall prepare and the Parties shall negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 15.5.4(c).

(i) **Continued Exploitation.** At Pfizer's request [***], Licensee shall continue on-going Exploitation with respect to such Terminated Territory, for a mutually agreed-upon period following the termination of this Agreement with respect to the Terminated Territory, which period shall not be less than [***] unless otherwise agreed to by the Parties. For avoidance of doubt, if Pfizer chooses not to continue a Clinical Trial initiated by Licensee pursuant to this Section 15.5.4(c)(i), [***] of winding down such Clinical Trial, including compliance with any ethical or other requirements imposed by an applicable Regulatory Authority.

(ii) **Technology Transfer.** At Pfizer's request, Licensee shall make available to Pfizer all currently available records and data which exist and are Controlled by Licensee with respect to such Terminated Territory, as of the effective date of termination, and are necessary or useful for Pfizer to continue Exploiting the Products in such Terminated Territory.

(iii) **Regulatory Matters.** At Pfizer's request, Licensee shall transfer and assign to Pfizer (or its designee) all Regulatory Approvals and Regulatory Filings held by Licensee with respect to such Terminated Territory, *provided* that if such transfer and assignment is not permitted by the applicable Regulatory Authority, Licensee shall permit Pfizer to cross-reference and rely upon such Regulatory Approvals and Regulatory Filings. Licensee shall make available to Pfizer copies of all regulatory documentation and records related to such Terminated Territory, including information contained in the regulatory and safety databases. The Parties shall cooperate to ensure the prompt transition of regulatory responsibilities with respect to such Terminated Territory, from Licensee to Pfizer.

(iv) **Trademarks.** Pfizer shall have, and Licensee does hereby grant to Pfizer, a fully paid-up, royalty-free, worldwide (except in the event that Pfizer terminates this Agreement with respect to a Terminated Territory, and such Terminated Territory is in the U.S. or Japan, in which case, such license shall be solely for the Terminated Territory) transferable, sublicensable, perpetual and irrevocable license to use the Licensee Product Trademarks associated with all Products with respect to the Terminated Territory, solely for the purpose of using, Developing, Commercializing and Manufacturing with respect to the Terminated Territory. Pfizer shall have a transitional license to use Licensee's Trademarks and promotional materials solely for the purpose of using, Developing, Commercializing and Manufacturing all Products with respect to a Terminated Territory.

(v) **Inventory and Supply.** At Pfizer's request, Licensee shall transfer to Pfizer (or its designee) all TL1A Antibody and Product, components and in-process inventory held by Licensee with respect to the Terminated Territory, as of such date of termination. At Pfizer's request, if Licensee has sublicensed to a CMO to Manufacture any Products with respect to the Terminated Territory, Licensee shall promptly assign such sublicense to Pfizer, or if not, Licensee shall continue to Manufacture or have Manufactured with respect to any Products with respect to the Terminated Territory, for a period of not less than [***], including, at Pfizer's request, a reasonable stock build. Pfizer shall pay to Licensee [***] of manufacturing associated with inventory and any TL1A Antibody or Product received by Pfizer pursuant to this Section 15.5.4(c)(v).

(vi)

Third Party Agreements. At Pfizer's request, to the extent Licensee is able to do so, Licensee shall assign to Pfizer (or its designee) any agreements with Third Parties with respect to the Development, Commercialization and Manufacture in the Terminated Territory. With respect to Third Party agreements that Licensee is not able to assign to Pfizer, Licensee shall cooperate to give Pfizer the benefit of such contracts for a reasonable transitional period.

15.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, (a) the provisions of Sections 1 (Definitions), 8 (Records; Audit Rights), 9.1 (Pre-existing IP), Sections 11.1 through 11.3 (Confidentiality), 13 (Indemnification), 14 (Limitation of Liability), 15.5 (Effects of Termination), 15.6 (Survival), 17 (Insurance) and 18 (General Provisions) shall survive expiration or termination of this Agreement and (b) [***]. If this Agreement is terminated with respect to a Terminated Territory, but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to such Terminated Territory (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety or as otherwise necessary for any of Pfizer and its Affiliates and its and their sublicensees to exercise their rights to such Terminated Territory) and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Territory and be of no further force and effect.

15.7 365(n) Rights. All rights and licenses now or hereafter granted to Licensee under or pursuant to this Agreement, including Sections 2.1.1 and 2.1.2, are rights to “intellectual property” as defined in Section 101(35A) of Title 11 of the United States Bankruptcy Code (the “**Bankruptcy Code**”). Pfizer hereby grants to Licensee a right of access and to obtain possession of and to benefit from the Licensed Know-How, which constitute “embodiments” of intellectual property pursuant to Section 365(n) of the Bankruptcy Code. Pfizer agrees not to interfere with Licensee’s exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use commercially reasonable efforts to assist Licensee to obtain such intellectual property and embodiments thereof in the possession or control of Affiliates or Third Parties as reasonably necessary or desirable for Licensee to exercise such rights and licenses in accordance with this Agreement. The Parties acknowledge and agree that all payments by Licensee to Pfizer under this Agreement, other than Licensee Royalties, do not constitute “royalties” within the meaning of Bankruptcy Code § 365(n) or relate to licenses of intellectual property hereunder. Conditioned upon satisfaction of the requirements of Section 365(b) of the Bankruptcy Code, Pfizer hereby consents to assumption of this Agreement in a case filed by or against Licensee under the Bankruptcy Code.

16. PUBLICITY; PUBLICATIONS.

16.1 Use of Names. Subject to Pfizer’s rights pursuant to Section 15.5.3(c)(iv), neither Party (nor any of its Affiliates or agents) shall use the registered or unregistered Trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance; *provided, however*, that Licensee and any of its Affiliates or sublicensees may state publicly that Licensee has received, or been sublicensed under, a license from Pfizer to Exploit the TL1A Antibody and Products.

16.2 Press Releases. The Parties acknowledge that one or both Parties, either singly or jointly, may desire to publish one or more press releases relating to this Agreement, the rights granted hereunder, and developments made thereto. However, each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; *provided* that a Party desiring to make such public disclosure may issue such press release or public announcement without such prior written consent by the other Party if (a) the entire contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (b) such press release or public announcement does not materially differ from a previously issued press release or other publicly available information. Neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law or the rules of any recognized stock exchange so long as the disclosing Party provides the other Party at least [***] prior written notice to the extent practicable and only discloses information to the extent required by Applicable Law or the rules of any recognized stock exchange.

16.3 Publications. During the Term, subject to the final sentence of this Section 16.3, Licensee shall have the sole right to make any academic, scientific or medical publication or public presentation related to the TL1A Antibody and Products; *provided* that written copies of such proposed publication or presentation shall be submitted to Pfizer for review no later than [***] before submission for publication or presentation (the “**Review Period**”). [***]

17. INSURANCE

17.1 Licensee Insurance Requirements. Licensee will maintain during the Term and until the later of (a) [***] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Products have expired, commercial general liability insurance from a minimum “A-” AM Best rated insurance company, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than [***] U.S. Dollars per occurrence and [***] U.S. Dollars in the aggregate. Licensee has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Licensee’s liability hereunder. Such policies shall name Pfizer and its Affiliates as additional insured via form CG20101185 or its equivalent (usually for US, Canada and Puerto Rico exposures) or indemnify Pfizer and its Affiliates, as principal (usually for rest of world exposures) and provide a waiver of subrogation in favor of Pfizer and its Affiliates. Licensee shall also maintain statutory workers’ compensation and employers liability with a minimum of [***] U.S. Dollars per occurrence. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to Pfizer or its Affiliates. Any deductibles or retentions for such insurance shall be assumed by Licensee.

17.2 Licensee Policy Notification. Licensee shall provide Pfizer with certified copies of such policies or original (electronic is acceptable) certificates of insurance evidencing such insurance (a) prior to execution by both Parties of this Agreement, and (b) the earlier of annually thereafter or prior to expiration of any one coverage. Licensee shall provide that Pfizer shall be given at least [***] written notice prior to cancellation, termination or any material change to restrict the coverage or reduce the limits afforded.

17.3 Pfizer Insurance Requirements. Pfizer, as sponsor of the UC Study, will maintain during the Term and until the later of (a) [***] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Products have expired, commercial general liability insurance from a minimum "A-" AM Best rated insurance company, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than [***] U.S. Dollars per occurrence and [***] U.S. Dollars in the aggregate. Pfizer has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Pfizer's liability hereunder. Such policies shall name Licensee and its Affiliates as additional insured via form CG20101185 or its equivalent (usually for US, Canada and Puerto Rico exposures) or indemnify Licensee and its Affiliates, as principal (usually for rest of world exposures) and provide a waiver of subrogation in favor of Licensee and its Affiliates. Pfizer shall also maintain statutory workers' compensation and employer's liability with a minimum of [***] U.S. Dollars per occurrence. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to Licensee or its Affiliates. Any deductibles or retentions for such insurance shall be assumed by Pfizer. Pfizer's insurance obligations can be met through a combination of insurance and/or self-insurance.

17.4 Pfizer Policy Notification. Pfizer shall provide Licensee with original (electronic is acceptable) certificates of insurance evidencing such insurance (a) prior to execution by both Parties of this Agreement, and (b) the earlier of annually thereafter or prior to expiration of any one coverage. Pfizer shall provide that Licensee shall be given at least [***] written notice prior to cancellation, termination or any material change to restrict the coverage or reduce the limits afforded.

18. GENERAL PROVISIONS

18.1 Assignment. For purposes of this Section 18.1, any Change of Control shall be deemed an assignment. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) either Party may assign to a Third Party such Party's rights to receive some or all of the Fees payable hereunder, (b) either Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of other Party, *provided* that Licensee shall not assign all or substantially all of its rights and obligations hereunder to one or more of its Affiliates (other than [***] or any direct or indirect wholly owned subsidiary of [***]) without the prior written consent of Pfizer; and (c) either Party may assign this Agreement in connection with a Change of Control of such Party. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

18.2 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

18.3 Governing Law; Dispute Resolution.

18.3.1 This Agreement shall be governed by and construed in all respects in accordance with the internal laws of the State of New York, as such laws are applied to agreements among New York residents entered into and performed entirely within New York, without giving effect to conflict-of-law principles thereof.

18.3.2 With support from the Alliance Managers, the Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or action arising from or related to this Agreement or the breach thereof. Subject to Section 18.3.8, in the event that the Parties cannot resolve such dispute, controversy or action within a period of [***] from when the dispute, controversy or action is first identified in writing by the Party raising or asserting such dispute, controversy or action, then the matter shall be referred to designated senior executives of the Parties for resolution by the sending of a notice of dispute(s) for executive resolution (a "Notice of Dispute(s) for Executive Resolution"). The designated senior executives shall endeavor to meet in person or by means of telephone conference, video conference or similar communications equipment by means of which all Persons participating in the meeting can hear and speak to each other, and where such participation by the Parties' designated senior executives shall constitute presence in person at the meeting, within [***] following transmittal of the Notice of Dispute(s) for Executive Resolution. Each Party shall be entitled to name substitute senior executives upon written notice to the other Party. The foregoing duties may be delegated to the extent the person delegated with such duties is duly authorized to enter into the foregoing resolution without seeking any additional approval within the respective Party.

18.3.3 Except as expressly set forth in Section 18.3.8, if the Parties do not fully settle any dispute, controversy or action referred to the senior executives of the Parties within [***] of it being referred to them, and a Party wishes to pursue the matter, then such dispute, controversy or action that is not an Excluded Action shall be finally resolved by binding arbitration administered by the American Arbitration Association ("AAA") pursuant to AAA's Commercial Arbitration Rules then in effect.

18.3.4 The arbitration shall be conducted by a panel of three (3) neutral arbitrators, each of whom shall have significant legal or business experience in the pharmaceutical industry, and none of whom shall be a current or former employee or director, or a current significant shareholder, of either Party or any of their respective Affiliates or sublicensees; and within [***] after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within [***] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, then on the [***] after the initiation of arbitration, the two (2) Party-selected arbitrators shall make a written request to AAA to appoint a third (3rd) arbitrator. AAA shall appoint such third (3rd) arbitrator within [***] of being notified by the two (2) Party-selected arbitrators. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

18.3.5 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party has the right to file an early dispositive motion seeking a determination on the issue of whether a material breach has occurred under Section 15.2, and the arbitrators will promptly rule on such motion. The arbitrators' authority to award punitive or any other type of damages not measured by a Party's compensatory damages shall be subject to the limitation set forth in Section 14.1. [***]

18.3.6 Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither Party nor an arbitrator may disclose the existence, content or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable action based on the dispute, controversy or action would be barred by the applicable statute of limitations in New York.

18.3.7 The term "**Excluded Action**" means a dispute, controversy or action that concerns (i) the construction, scope, validity, enforceability, inventorship or infringement, misappropriation or other violation of any Intellectual Property Rights; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

18.3.8 Either Party may bring an action in any court of competent jurisdiction to resolve any Excluded Action, and no Excluded Action shall be subject to arbitration pursuant to Sections 18.3.3 or 18.3.4. Any Excluded Action brought by either Party pursuant to this Section 18.3.8 shall be venued exclusively in the United States District Court for the Southern District of New York ("**SDNY**"), or if the SDNY does not have the jurisdiction to hear such Excluded Action, in a state court located in New York county, and each Party expressly and irrevocably consents and submits to the jurisdiction of such courts having appropriate jurisdiction in connection with any such legal action.

18.3.9 EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING FROM OR RELATED TO THIS AGREEMENT OR THE BREACH THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT ARISE FROM OR RELATE TO THIS AGREEMENT OR THE BREACH THEREOF, INCLUDING CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

18.4 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of Section 3 or Section 11, in each case, is not performed in accordance with its specific terms of this Agreement or is otherwise breached. It is accordingly agreed that either Party shall be entitled to an injunction or injunctions to prevent breaches of Section 3 or Section 11 and to enforce specifically the terms and provisions of such section of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which such Party is entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate. The Parties acknowledge and agree that damages, to the extent incurred by and awarded to, a Party are an appropriate remedy for any breach or violation of any other provision of this Agreement and that the Parties do not intend for any other provision of this Agreement to be specifically enforceable.

18.5 Force Majeure. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of any Governmental Authority or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or any other cause outside of the reasonable control of such Party (each, a “**Force Majeure Event**”), *provided* that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for three hundred sixty-five (365) days or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

18.6 Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

18.7 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Pfizer and Licensee, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership, joint venture, employment, franchise, agency or fiduciary or similar relationship for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

18.8 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

18.9 Notices. All notices, consents, waivers, and other communications required or permitted to be given hereunder shall in all cases be delivered by email (with receipt of such email acknowledged by a non-automated response by the applicable recipient within two (2) Business Days of receipt, or, in the event that receipt is not so acknowledged by the applicable recipient, with delivery by an internationally recognized courier service of a confirmatory hardcopy without undue delay) and shall be deemed given when sent, *provided* that (a) there is no “bounce back” message and (b) such email is sent on a Business Day prior to 6:00 pm local time of the recipient, and on the next Business Day if sent at any other time, but may, as a second method of delivery, also be delivered (i) by personal delivery or (ii) by an internationally recognized overnight courier service, to the applicable address set forth below, unless another address has been previously specified in writing by such Party in the manner set forth above.

If to Pfizer:

Pfizer Inc.
[***]

If to Licensee:

[***]

If to Roivant:

Roivant Sciences Ltd.
[***]

18.10 Further Assurances. Licensee and Pfizer hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

18.11 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except for (a) the provisions of Section 13, which shall be for the benefit of the Licensee Indemnitees and the Pfizer Indemnitees, (b) the provisions of Section 18.1, which shall be for the benefit of the Persons contemplated thereby, and (c) this Section 18.11 in respect of the sections set forth under the foregoing clauses (a) and (b).

18.12 Entire Agreement; Confidentiality Agreement.

18.12.1 This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including the CDA. The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information (as defined in the CDA) disclosed by Pfizer or its Affiliates pursuant to the CDA shall be considered Pfizer's Confidential Information and subject to the terms set forth in this Agreement.

18.12.2 In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

18.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The Parties agree that execution of this Agreement by industry standard electronic signature software or by exchanging executed signature pages in .pdf format via e-mail shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or related to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

18.14 Cumulative Remedies. 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 law.

18.15 Performance by Affiliates. Any obligation of either Party under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at such Party's sole and exclusive option, by any Affiliate of such Party that it causes to satisfy, meet or fulfill such obligation, in whole or in part, *provided* that such Party shall remain liable hereunder for the performance by its Affiliates of any such obligations.

18.16 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signature pages to follow]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

PFIZER INC.

By: [***] _____

Name: [***] _____

Title: [***] _____

[Signature Page to License and Collaboration Agreement]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

[***]

By: [***] _____

Name: [***] _____

Title: [***] _____

And solely with respect to Section 11.4:

ROIVANT SCIENCES LTD.

By: [***] _____

Name: [***] _____

Title: [***] _____

[Signature Page to License and Collaboration 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.**

INVESTOR RIGHTS AGREEMENT

THIS INVESTOR RIGHTS AGREEMENT (this “**Agreement**”) is made as of November 21, 2022, by and among [***] a Delaware corporation with offices at [***] (the “**Company**”), Roivant Sciences Ltd., an exempted limited company incorporated under the laws of Bermuda with its registered office at [***] (“**Roivant**”), Pfizer Inc., a Delaware corporation with offices at [***] (“**Pfizer**”) and each other Person that becomes an “**Investor**” hereunder after the date hereof in accordance with this Agreement. Each of the Company and the Investors shall be referred to herein as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, the Company, Roivant, and Pfizer are parties to that certain Stock Purchase Agreement dated as of the date hereof (as it may be amended from time to time, the “**Stock Purchase Agreement**”) and [***] a wholly-owned Subsidiary of the Company, and Pfizer are parties to that certain License and Collaboration Agreement dated as of the date hereof (as it may be amended from time to time, the “**License Agreement**”); and

WHEREAS, in order to induce the Company, Roivant, and Pfizer to enter into the Stock Purchase Agreement and to induce [***] and Pfizer to enter into the License Agreement, and to perform the transactions contemplated thereby and hereby, the Investors and the Company hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register certain of their Equity Securities, to receive certain information from the Company, and certain other matters as set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I DEFINITIONS

“**Affiliate**” means, with respect to any specified Person, any other Person who directly or indirectly controls, is controlled by, or is under common control with such Person, including any direct or indirect parent or Subsidiary of such Person (it being understood, for the avoidance of doubt, that a Person is only deemed an Affiliate of another Person at such times that the criteria set forth in this definition apply). “**Affiliated**” has a correlative meaning.

“**Beneficially Own**” or “**Beneficial Ownership**” has the meaning assigned to such term in Rule 13d-3 under the Exchange Act, and a Person’s Beneficial Ownership of securities shall be calculated in accordance with the provisions of such Rule, in each case irrespective of whether or not such Rule is actually applicable in such circumstance.

“**Board**” means the Board of Directors of the Company.

“**Business Day**” means a day other than a Saturday, Sunday or a national or public holiday, on which commercial banks in the State of New York, United States, and London, England are open for the transaction of commercial banking business.

“**Change of Control**” means [***].

“**Certificate of Incorporation**” means the Company’s Certificate of Incorporation, as amended or restated from time to time.

“**Common Stock**” means shares of the Company’s common stock, par value \$0.01 per share.

“**Contract**” means any contract, lease, license, sublicense, indenture, loan, note, agreement or other legally binding commitment, arrangement or undertaking (whether written or oral and whether express or implied).

“**control**” (including, with correlative meanings, the terms “controlled by” and “under common control with”), as used with respect to any Person or group of Persons, means (a) possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the Person, whether through the Beneficial Ownership of voting securities, by Contract or otherwise or (b) Beneficial Ownership of at least fifty percent (50%) of the aggregate voting rights of issued and outstanding equity securities that are entitled to vote at a general meeting of such Person.

“**Corporate Strategic Relationship**” means one or more agreements, arrangements or transactions that establishes, effects, amends or modifies any of the following; [***]

“Damages” means any loss, damage, claim or liability (joint or several) to which a Person is subject or may become subject under the Securities Act, the Exchange Act, or other applicable Laws or Orders, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (a) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (b) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (c) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any other applicable securities Law or Order.

“Designated Affiliate” means (a) with respect to the Company, Roivant Sciences Ltd. and any Person controlled by Roivant Sciences Ltd., (b) with respect to Pfizer, any Person controlled by Pfizer and (c) with respect to any other Person that becomes an Investor hereunder, the ultimate parent entity of such Person, and each other Person controlled by such ultimate parent entity.

“Equity Securities” means, without duplication, (a) the Shares, (b) any other class or series of equity security or equity-linked security issued by the Company and (c) any other securities or rights (including options and warrants) convertible into or exchangeable or exercisable for (in each case, directly or indirectly) Shares or any other class or series of equity or equity-linked securities issued by the Company.

“Exchange Act” means the Securities Exchange Act of 1934.

“Excluded Registration” means: (a) a registration relating to the sale of securities to employees of the Company or a Subsidiary of the Company pursuant to an equity option, equity purchase, or similar plan; (b) a registration relating to an SEC Rule 145 transaction; (c) a registration in connection with an exchange offer; (d) a registration in which the only securities being registered are securities issuable upon conversion of other securities that are also being registered; (e) a registration relating to the acquisition of, or combination with, another Person, including any registration on Form S-4 or F-4 (or any successor thereto) or its foreign equivalent; or (f) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities.

“Exempted Securities” means: (a) Equity Securities issued by reason of a dividend, share split, split-up or other dividend or distribution on Equity Securities, in each case, provided that such Equity Securities are issued to all Holders, pro rata to the number of Equity Securities held or otherwise in accordance with the terms of such Equity Securities; (b) Equity Securities issued to officers, employees or directors of, or consultants or advisors to, the Company or any of its Subsidiaries pursuant to a plan, agreement or arrangement approved by the Board; (c) Equity Securities issued pursuant to an employee stock option plan, management incentive plan, restricted stock plan, stock purchase plan or stock ownership or similar benefit plan, program or agreement as approved by the Board; (d) Equity Securities issued upon the exercise or conversion of other Equity Securities, in each case provided such issuance is pursuant to the terms of such Equity Security; (e) Equity Securities issued to banks, equipment lessors, other financial institutions, or to real property lessors or other Persons, pursuant to debt financing, equipment leasing or real property leasing transactions approved by the Board; (f) Equity Securities issued to suppliers or third party service providers in connection with the provision of goods or services pursuant to transactions approved by the Board; (g) Equity Securities issued pursuant to the acquisition of, or combination with or into, another Person, business or assets by the Company or any of its Subsidiaries approved by the Board; (h) Equity Securities issued in connection with sponsored research, collaboration, technology license, development, marketing or other similar agreements or strategic partnerships approved by the Board; or (i) Equity Securities issued in connection with a bona fide strategic partnership or commercial arrangement with a Person approved by the Board; or (j) [***].

“FINRA” means the Financial Industry Regulatory Authority, Inc.

“Form S-3” means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

“Free Writing Prospectus” means a free writing prospectus, as defined by Rule 405 promulgated under the Securities Act.

“Global Trade Control Laws” means the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the U.S. economic sanctions rules and regulations implemented under statutory authority or the President’s Executive Orders and administered by the U.S. Department of the Treasury Office of Foreign Assets Control; E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012; other E.U. Council sanctions regulations, as implemented in E.U. Member States; United Nations sanctions policies; all relevant regulations and legislative instruments made under any of the above; other applicable economic sanctions, export and import control laws, and other applicable laws, regulations, legislation, Orders and requirements imposed by a relevant Governmental Authority.

“Governmental Authority” means any U.S. or non-U.S. federal, state, local or other governmental, administrative or regulatory (including self-regulatory) authority, body, agency, court, tribunal or similar entity, including any taxing authority, any work council or similar labor entity or any department, bureau, division or instrumentality of any of the foregoing.

“Healthcare Laws” means the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the FD&C Act (21 U.S.C. §§ 301 et seq.), the Controlled Substances Act (21 U.S.C. §§ 801 et seq.), Section 1128G of the Social Security Act (the Physician Payment Sunshine Law), The Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1, et seq.), the Medicare Program (Title XVIII of the Social Security Act), the Medicaid Program (Title XIX of the Social Security Act), the regulations promulgated pursuant to such laws, requirements of the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, requirements of Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126), state pharmaceutical assistance programs and regulations under such laws, and the U.S. FDA Good Clinical Practices (GCP) (21 C.F.R. Parts 50, 54, 56, 58 and 312), Good Laboratory Practices (GLP) (21 C.F.R. Part 58), and Good Manufacturing Practices (GMP) (21 C.F.R. Parts 210-211 and 820).

“**Holders**” means, collectively, the Investors and their respective valid transferees that are holders of Registrable Securities and Party to this Agreement.

“**Immediate Family Member**” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

“**Investors**” means the Persons named on Schedule 1 hereto and each Person to whom the rights of such parties are assigned pursuant to Section 6.1 (*Successors and Assigns; Third Party Beneficiaries*) each Person who hereafter becomes a signatory to this Agreement pursuant to Section 6.14 (*Additional Investors*) and any one of them, as the context may require; provided, however, that any such Person shall cease to be considered an Investor for purposes of this Agreement if, together with its Designated Affiliates, it ceases to Beneficially Own at least [***] of the aggregate voting rights of issued and outstanding Equity Securities that are entitled to vote at a meeting of stockholders of the Company; provided, however, that [***].

“**Law**” means any international, supranational, national, federal, state or local law, constitution, treaty, convention, statute, ordinance, code, rule, regulation, common law or other similar requirement enacted, adopted, promulgated or applied by any Governmental Authority.

“**Listing Event**” means (a) the Company’s first underwritten public offering of its Shares or any other Equity Securities of the Company pursuant to an effective registration statement filed under the Securities Act or its foreign equivalent, (b) any transaction (including a “direct listing” or “reverse merger IPO” transaction) pursuant to which the Company or any successor entity first becomes subject to the periodic reporting requirements of Section 13 or 15(d) of the Exchange Act or any foreign equivalent, or (c) an acquisition of the Company by, or consolidation, amalgamation, merger, reorganization or other business combination involving the Company with or into, a special purpose acquisition company that is publicly listed on a national or foreign securities exchange and that does not conduct any material business or maintain any material assets other than cash.

“**New Securities**” means Equity Securities, whether or not currently authorized.

“**Order**” means any judgment, order, injunction, decision ruling, writ or decree of any Governmental Authority.

“**Person**” means any individual, general or limited partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated organization, joint venture, firm, association or other entity or organization (whether or not a legal entity), including any Governmental Authority.

“**Preferred Director**” means any Series A-1 Preferred Director or Series A-2 Preferred Director.

“**Preferred Stock**” means Series A-1 Preferred Stock and Series A-2 Preferred Stock.

“**Qualified Listing Event**” means (a) the Company’s first underwritten public offering of its capital stock pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, or its foreign equivalent, (b) any transaction (including a “direct listing” or “reverse merger IPO” transaction) pursuant to which the Company or any successor entity first becomes subject to the periodic reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, or any foreign equivalent, or (c) an acquisition of the Company by, or consolidation, amalgamation, merger, reorganization or other business combination involving the Company with or into, a special purpose acquisition company that is publicly listed on a national or foreign securities exchange and that does not conduct any material business or maintain any material assets other than cash, in each case of clauses (a)–(c), which results in [***].

“**Registrable Securities**” means (a) the Common Stock held by the Investors, including Common Stock issued or issuable (directly or indirectly) upon conversion, exchange or exercise of any other securities of the Company, acquired by the Investors on or after the date hereof; and (b) Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the securities referenced in clause (a); excluding in all cases, any Registrable Securities Transferred by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Section 6.1 (*Successors and Assigns; Third Party Beneficiaries*) and excluding for purposes of Article II (*Registration Rights*) any securities for which registration rights have terminated pursuant to Section 2.13 (*Termination of Registration Rights*).

[***]

“**Relatives**” means, with respect to any individual, collectively, the spouse, parents, siblings and descendants of such individual and their respective issue (whether by blood or adoption and including stepchildren) and the spouses of such persons.

“**Requisite Preferred Director Vote**” means the vote of a majority of the Series A-2 Preferred Directors then seated.

“**Restricted Market**” means, as applicable under Global Trade Control Laws, the Crimean Peninsula, Cuba, Iran, North Korea, and Syria.

“**Restricted Party**” means any individual or entity on any of the following “**Restricted Party Lists**”: the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities, as published by the U.S. Health and Human Services – Office of Inspector General; any lists of prohibited or debarred parties established under the FD&C Act; the list of persons and entities suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Authorities of the countries that have jurisdiction over the activities conducted by the Company.

“**Restricted Securities**” means the securities of the Company required to bear the legend set forth in Section 2.12(b) (*Restrictions on Transfer*) hereof.

“**Sale Transaction**” means [***].

“**SEC**” means the United States Securities and Exchange Commission.

“**SEC Rule 144**” means Rule 144 promulgated by the SEC under the Securities Act.

“**SEC Rule 145**” means Rule 145 promulgated by the SEC under the Securities Act.

“**Securities Act**” means the Securities Act of 1933.

“**Selling Expenses**” means all underwriting discounts, selling commissions, and share transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder.

“**Series A-1 Preferred Director**” means any director of the Company that the holders of record of Series A-1 Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation.

“**Series A-1 Preferred Stock**” means shares of the Company’s Series A-1 Preferred Stock, par value \$0.01 per share.

“**Series A-2 Preferred Director**” means any director of the Company that the holders of record of Series A-2 Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation.

“**Series A-2 Preferred Stock**” means shares of the Company’s Series A-2 Preferred Stock, par value \$0.01 per share.

“**Shares**” means shares of the Common Stock and the Preferred Stock.

“**Standoff Period**” means [***].

“**Subsidiary**” means, with respect to any Person, any other Person with respect to which such first Person (a) possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the Beneficial Ownership of voting securities, by Contract or otherwise or (b) Beneficially Owns at least fifty percent (50%) of the aggregate voting rights of issued and outstanding Equity Securities that are entitled to vote at a general meeting of such Person.

“**Transaction Documents**” has the meaning given to such term in the Stock Purchase Agreement.

“**Transfer**” by any Person means to, directly or indirectly, sell, transfer, assign, pledge, encumber, mortgage, hypothecate or otherwise dispose of or transfer (by the operation of Law or otherwise), either voluntarily or involuntarily.

ARTICLE II REGISTRATION RIGHTS

Section 2.1 **Form S-3 Demand Registration.**

(a) From and after a Listing Event, if at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from any Holder (the “**Initiating Holder**”) that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Initiating Holder having an anticipated aggregate offering price, net of Selling Expenses, of at least [***], then the Company shall, (i) within [***] after the date such request is given, give notice of such demand (a “**Demand Notice**”) to all Holders other than the Initiating Holder; and (ii) as soon as practicable, and in any event within [***] after the date such request is given by the Initiating Holder, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by the Initiating Holder and by any other Holder, as specified by notice given by each such Holder to the Company within [***] of the date the Demand Notice is given, and in each case, subject to the limitations of Section 2.1(b) (*Form S-3 Demand Registration*) and Section 2.3 (*Underwriting Requirements*).

(b) Notwithstanding the foregoing obligations, if the Company furnishes to the Initiating Holder a certificate signed by any of the Company's authorized officers stating that in the good faith judgment of the Board it would or would reasonably be expected to be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing or suspend the use of such registration statement (a "**Suspension Period**"); provided that the Company shall not be permitted to exercise a Suspension Period for more than a total of [***] consecutive calendar days or more than [***] total calendar days in any [***] period; and provided further that the Company shall not register any securities for its own account or that of any other stockholder during any such Suspension Period other than an Excluded Registration. Each Holder agrees that, upon receipt of notice from the Company of the occurrence of a Suspension Period, such Holder shall cease offering, selling or distributing the Registrable Securities owned by such Holder until the Company notifies such Holder that such Suspension Period has ended.

(c) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(a) (*Form S-3 Demand Registration*): (i) during the period that is [***] before the Company's good faith estimate of the date of filing of, and ending on a date that is [***] after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected [***] registrations pursuant to Section 2.1(a) (*Form S-3 Demand Registration*) within the [***] period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Section 2.1(c) (*Form S-3 Demand Registration*) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holder withdraws its request for such registration, elects not to pay the registration expenses therefor, and forfeits its right to one demand registration statement pursuant to Section 2.6 (*Expenses of Registration*), in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Section 2.1(c) (*Form S-3 Demand Registration*); provided, that if such withdrawal is during a period the Company has deferred taking action pursuant to Section 2.1(b) (*Form S-3 Demand Registration*), then the Initiating Holders may withdraw their request for registration and such registration will not be counted as "effected" for purposes of this Section 2.1(c) (*Form S-3 Demand Registration*).

Section 2.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its Shares or other Equity Securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration, which notice shall describe the amount and type of securities to be included in such offer, the proposed manner of distribution and the name of the managing underwriter (if any and if known at such time). Upon the request of each Holder given within [***] after such notice is given by the Company, the Company shall, subject to the provisions of Section 2.3 (*Underwriting Requirements*) cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 (*Company Registration*), before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Section 2.6 (*Expenses of Registration*).

Section 2.3 Underwriting Requirements.

(a) If, pursuant to Section 2.1 (*Form S-3 Demand Registration*), the Initiating Holder intends to distribute the Registrable Securities covered by its request by means of an underwriting, it shall so advise the Company as a part of their request made pursuant to Section 2.1 (*Form S-3 Demand Registration*), and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to the Initiating Holder. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Section 2.4(e) (*Obligations of the Company*)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting; [***]. Notwithstanding any other provision of this Section 2.3 (*Underwriting Requirements*), if the managing underwriter(s) advise(s) the Initiating Holder in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holder shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holder, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities (held by non-Holders) are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of Shares or other Equity Securities pursuant to Section 2.2 (*Company Registration*), the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their sole discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the number of Registrable Securities included in the offering be reduced below [***] of the total number of securities included in such offering, unless such offering is a Qualified Listing Event, in which case the selling Holders may be excluded further if the Company (and, if applicable, the underwriters) makes the determination described above and no other securities of the Company held by others are included in such offering. For purposes of the provision in this Section 2.3(b) (*Underwriting Requirements*) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Section 2.1 (*Form S-3 Demand Registration*), a registration shall not be counted as “effected” if, as a result of an exercise of the underwriter’s cutback provisions in Section 2.3(a) (*Underwriting Requirements*), fewer than [***] of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

Section 2.4 Obligations of the Company. Whenever required under this Article II (*Registration Rights*) to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use commercially reasonable efforts to cause such registration statement to become effective and, upon the request of any Holder, keep such registration statement effective for a period of up to [***] or, if earlier, until the distribution contemplated in the registration statement has been completed; provided that: (i) such [***] period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Shares or other Equity Securities, as applicable, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such [***] period shall be extended for up to [***], if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement and provide the selling Holders and their counsel a reasonable opportunity to review and comment on such amendments and supplements prior to filing them with the SEC;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as such Holders may reasonably request in order to facilitate the disposition of their Registrable Securities and provide such Holders and their counsel a reasonable opportunity to review and comment on such prospectus prior to filing it with the SEC;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) notify each selling Holder of such Registrable Securities, at any time when a prospectus or Free Writing Prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading (which, for the avoidance of doubt, will commence a Suspension Period) and, at the request of any such Holder, the Company will, as soon as reasonably practicable, file and furnish to all such Holders a supplement or amendment to such prospectus or Free Writing Prospectus so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus will not contain an untrue statement of a material fact or omit to state any material fact necessary to make the statements therein not misleading in light of the circumstances under which they were made;

(i) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(j) use its commercially reasonable efforts to furnish, at the request of any selling Holder requesting registration of Registrable Securities pursuant to this Article II, if such securities are being sold through underwriters, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, (ii) a "negative assurances letter", dated such date, of the legal counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering and (iii) a letter dated such date, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters;

(k) in connection with an underwritten offering, the Company shall cause its officers to use their commercially reasonable efforts to support the marketing of the Registrable Securities covered by such offering (including participation in "road shows" or other similar marketing efforts);

(l) cooperate with the selling Holder and each underwriter or agent participating in the disposition of Registrable Securities and their respective counsel in connection with any filings required to be made with FINRA, including the use of commercially reasonable efforts to obtain FINRA's pre-clearance or pre-approval of the registration statement and applicable prospectus upon filing with the SEC;

(m) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(n) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

Section 2.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Article II (*Registration Rights*) with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

Section 2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Article II (*Registration Rights*), including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; [***], shall be borne and paid by the Company; provided that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Section 2.1 (*Form S-3 Demand Registration*), if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Section 2.1(a) (*Form S-3 Demand Registration*); provided further that if, at the time of such withdrawal, (i) the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such material adverse change or (ii) if the Holders have withdrawn the request in connection with the deferral of a registration by the Company pursuant to Section 2.1(b) (*Form S-3 Demand Registration*), then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Section 2.1(a) (*Form S-3 Demand Registration*). All Selling Expenses relating to Registrable Securities registered pursuant to this Article II (*Registration Rights*) [***] shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

Section 2.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Article II (*Registration Rights*).

Section 2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Article II (*Registration Rights*):

(a) To the extent permitted by applicable Law or Order, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided that the indemnity agreement contained in this Section 2.8(a) (*Indemnification*) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by applicable Law or Order, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided that the indemnity agreement contained in this Section 2.8(b) (*Indemnification*) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Section 2.8(b) (*Indemnification*) and Section 2.8(d) (*Indemnification*) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Section 2.8 (*Indemnification*) of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8 (*Indemnification*), give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the Parties; provided that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.8 (*Indemnification*), to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.8 (*Indemnification*).

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Section 2.8 (*Indemnification*) but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Section 2.8 (*Indemnification*) provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any Party hereto for which indemnification is provided under this Section 2.8 (*Indemnification*), then, and in each such case, such Parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided that, in any such case (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement (net of any Selling Expenses paid by such Holder), and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Section 2.8(d) (*Indemnification*), when combined with the amounts paid or payable by such Holder pursuant to Section 2.8(b) (*Indemnification*), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and the Holders under this Section 2.8 (*Indemnification*) shall survive the completion of any offering of Registrable Securities in a registration under this Article II (*Registration Rights*), and otherwise shall survive the termination of this Agreement.

Section 2.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall use commercially reasonable efforts to:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the date of consummation of a Listing Event and for so long as the Company remains subject to the periodic reporting requirements under Sections 13 or 15(d) of the Exchange Act;

(b) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after 90 days after the applicable Listing Event), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies) and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

Section 2.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders, enter into any agreement with any holder or prospective holder of any securities of the Company that: (a) would provide to such holder the right to include securities in any registration on other than either (i) a pro rata basis with respect to the Registrable Securities or (ii) on a subordinate basis after all of the Holders have had the opportunity to include in the registration and offering all Registrable Securities that they wish to so include or (b) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

Section 2.11 “Market Stand-off” Agreement. Each Holder agrees that it will not, without the prior written consent of the Company and, if applicable, the managing underwriter, during the Standoff Period: (a) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise Transfer or dispose of, directly or indirectly, any Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Shares or (b) enter into any swap or other arrangement that Transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Shares or other securities, in cash, or otherwise. The foregoing provisions of this Section 2.11 (*“Market Stand-off” Agreement*) shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement or the Transfer of any shares to any Designated Affiliate of the Holder; provided that such Designated Affiliate shall agree to be bound by the provisions of this Section 2.11 (*“Market Stand-off” Agreement*) with respect to future Transfers; provided further that this Section 2.11 (*“Market Stand-off” Agreement*) shall be applicable to each Holder and transferee only if all officers and directors of the Company and stockholders with at least a [***] ownership of the issued and outstanding Common Stock (after giving effect to the conversion into Common Stock of all outstanding Preferred Stock) immediately prior to (x) in respect of a QLE Standoff Period, the Company entering into an underwriting, business combination or similar agreement in connection with a Qualified Listing Event and (y) in respect of a non-QLE Standoff Period, the Company entering into an underwriting agreement in respect of the applicable underwritten public offering, are subject to the same restrictions and the Company obtains a substantially identical agreement from all other Investors. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Company stockholders that are subject to such agreements, based on the number of shares subject to such agreements. The underwriters, if any, in connection with such Qualified Listing Event or other underwritten public offering of the Company’s Equity Securities under the Securities Act are intended third party beneficiaries of this Section 2.11 (*“Market Stand-off” Agreement*) and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the Company or the underwriters in connection with such registration or other transaction that are consistent with this Section 2.11 (*“Market Stand-off” Agreement*) or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Registrable Securities (and the Equity Securities of every other Person subject to the foregoing restriction) until the end of such restricted period.

Section 2.12 Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be Transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such Transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. Each Holder, if effecting a Transfer, will cause any proposed transferee of the Preferred Stock and the Registrable Securities to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate or instrument representing the Preferred Stock, the Registrable Securities, and any other securities issued in respect of such Preferred Stock or Registrable Securities, upon any split, dividend, recapitalization, merger, amalgamation, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Section 2.12(c) (*Restrictions on Transfer*)) be stamped or otherwise imprinted with a legend substantially in the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE WERE ORIGINALLY ISSUED ON _____, 20__, HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR APPLICABLE STATE SECURITIES LAWS ("STATE ACTS") AND MAY NOT BE TRANSFERRED, SOLD, ASSIGNED, PLEDGED, HYPOTHECATED OR OTHERWISE DISPOSED OF ("TRANSFERRED") IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR STATE ACTS OR AN EXEMPTION FROM REGISTRATION THEREUNDER.

THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE TRANSFERRED EXCEPT IN ACCORDANCE WITH THE PROVISIONS OF THE BYLAWS OF THE COMPANY, A CERTAIN INVESTOR RIGHTS AGREEMENT BY AND AMONG THE COMPANY AND CERTAIN STOCKHOLDERS OF THE COMPANY AND A CERTAIN RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT BY AND AMONG THE COMPANY AND CERTAIN STOCKHOLDERS OF THE COMPANY. ANY TRANSFEREE OF THESE SECURITIES TAKES SUBJECT TO THE TERMS THEREOF.

The Holders consent to the Company's making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on Transfer set forth in this Section 2.12 (*Restrictions on Transfer*).

(c) Each Holder, as a holder of Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Article II (*Registration Rights*). Before any Transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder shall give notice to the Company of its intention to effect such Transfer. Each such notice shall describe the manner and circumstances of the Transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either: (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed Transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed Transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to Transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to a Designated Affiliate of such Holder for no consideration; provided that, in the case of clause (y), each transferee agrees in writing to be subject to the terms of this Section 2.12 (*Restrictions on Transfer*). Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear, except if such Transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Section 2.12(b) (*Restrictions on Transfer*), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

(d) Notwithstanding the provisions of Sections Section 2.12(a) (*Restrictions on Transfer*) and 2.12(c) (*Restrictions on Transfer*) above, no such registration statement or opinion of counsel or "no action" letter shall be necessary for: (a) a transfer by a Holder to any of its Affiliates, (b) a transfer by a Holder that is a partnership, limited liability company or corporation to a partner, limited partner, retired partner, member, retired member or stockholder of a Holder; (c) a transfer to a Charity; (d) a transfer by gift, will or intestate succession of any partner to his or her spouse or to the siblings, lineal descendants or ancestors of such partner or his or her spouse; or (e) the transfer by a Holder exercising its co-sale rights under the Right of First Refusal and Co-Sale Agreement by and among the Company and the Investors and Common Holders named therein of even date herewith, as amended, if in each transfer under clauses (a), (b), (c) or (d) the prospective transferee agrees in all such instances in writing to be subject to the terms hereof to the same extent as if he or she were an original Holder hereunder.

(e) The rights to cause the Company to register Registrable Securities pursuant to this Section 2.12(e) (*Restrictions on Transfer*) may be assigned by a Holder to a transferee or assignee of Registrable Securities (for so long as such shares remain Registrable Securities) that (a) is a subsidiary, parent, general partner, limited partner, retired partner, member or retired member, of a Holder that is a corporation, partnership or limited liability company, (b) is a Holder's family member or trust for the benefit of an individual Holder, (c) acquires at least [***] of the then-outstanding Registrable Securities or (d) is an Affiliate of such Holder; provided, however, that (i) the transferor shall, within [***] after such transfer, furnish to the Company written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being assigned and (ii) such transferee shall agree to be subject to all restrictions set forth in this Agreement.

Section 2.13 Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Section 2.1 (*Form S-3 Demand Registration*) or Section 2.2 (*Company Registration*) shall terminate upon the earliest to occur of:

(a) the consummation of a Change of Control of the Company or the liquidation, winding up or other dissolution of the Company;

(b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration; and

(c) [***]

ARTICLE III INFORMATION RIGHTS.

Section 3.1 Delivery of Financial Statements. The Company shall deliver to each Investor:

(a) within [***] after the end of each fiscal year of the Company beginning with the fiscal year ended March 31, 2023: (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements to be to be (x) prepared in accordance with applicable Accounting Standards (as such term is defined in the License Agreement) and (y) audited commencing in the year in which the Company or any of its Affiliates achieves its first commercial sale of a Licensed Product (as defined in the License Agreement), with the audit to be conducted by an independent registered public accounting firm selected by the Company;

(b) within [***] after the end of each of the first three quarters of each fiscal year of the Company beginning with the fiscal quarter ending June 30, 2023, unaudited statements of income and a balance sheet for such fiscal quarter and as of the end of such fiscal quarter (respectively) to be prepared in accordance with applicable Accounting Standards (as such term is defined in the License Agreement) (except that such financial statements (i) may be subject to income tax or normal year end audit adjustments; and (ii) may not contain all notes thereto that may be required in accordance with applicable Accounting Standards). [***]

(c) [***]

If, for any period, the Company has any Subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to clauses (a) through (b) shall be the consolidated financial statements of the Company and all such consolidated Subsidiaries.

Notwithstanding anything else in this Section 3.1 (*Delivery of Financial Statements*) to the contrary and subject to applicable Law and Order, the Company may cease providing the information set forth in this Section 3.1 (*Delivery of Financial Statements*) during the period starting with the date thirty (30) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Section 3.1 (*Delivery of Financial Statements*) shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

Section 3.2 Access. Except in connection with any dispute involving the Company or any other Investor or any of their respective Affiliates, the Company shall, and shall cause each of its Subsidiaries to, provide each Investor (for the purpose of monitoring its investment in the Company) reasonable access to the Company's and each of its Subsidiaries' properties, books of account and records, and officers to discuss the Company's and such Subsidiaries' affairs, finances and accounts. All access pursuant to this Section 3.2 (*Access*) shall be conducted (i) during normal business hours of the Company or its Subsidiaries, as applicable, upon reasonable advance written notice to the Company, (ii) in such a manner as not to unreasonably interfere with the normal operations of the Company and its Subsidiaries, as applicable and (iii) at the Investor's sole cost and expense; provided, however, that the Company shall not be obligated pursuant to this Section 3.2 (*Access*) to provide access to any information, books, accounts, records or other material if (a) the Company reasonably determines in good faith that providing access to any such information is reasonably likely to result in a material competitive disadvantage or (b) providing access to any such information would reasonably be expected to (x) violate any applicable Law or Order, (y) jeopardize an attorney-client privilege or cause a loss of attorney work product protection or other privilege or protection, (z) violate a confidentiality obligation to a third party (provided that, the Company shall use reasonable efforts to provide an alternative means of providing access to such information to the maximum extent that would not reasonably be expected to result in a material competitive disadvantage or a loss of such legal privilege or protection or violate any such confidentiality obligations or contravene any applicable Law or Order).

Section 3.3 Termination of Information Rights. The covenants set forth in Section 3.1 (*Delivery of Financial Statements*) and Section 3.2 (*Access*) shall terminate and be of no further force or effect upon the earliest of: (i) immediately before the consummation of a Qualified Listing Event, (ii) the consummation of a Change of Control of the Company or (iii) the liquidation, winding up or other dissolution of the Company.

Section 3.4 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor or make decisions with respect to its investment in the Company) any information obtained from or on behalf of the Company or its Subsidiaries pursuant to the terms of this Agreement unless such information: (a) is known or available or becomes known or available to the public (other than as a result of a breach of this Section 3.4 (*Confidentiality*) by such Investor), (b) is or has been independently developed or conceived by such Investor without use of the Company's information or (c) is or has been made known or disclosed to such Investor by a third party without a known or reasonably expected breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information: (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary or useful to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Section 3.4 (*Confidentiality*); (iii) to any existing Affiliate, partner, member, stockholder, or wholly owned Subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and causes such Person to maintain the confidentiality of such information, or (iv) in the event that the Investor or anyone to whom it discloses information receives a request, or is legally required, to disclose all or any part of the information under the terms of a subpoena or other Order, provided that the Investor shall (a) promptly notify the Company of the existence, terms and circumstances surrounding such a request or requirement so that the Company may seek, at the Company's sole cost and expense, an appropriate protective order, other reasonable assurance that confidential treatment will be accorded to such information or other remedy, (b) cooperate with the Company in its efforts to obtain such an order, assurance or other remedy or to take steps to resist or narrow the scope of such request or requirement and (c) not oppose any action to obtain such protective order, assurance or other remedy. If, a protective order, other reasonable assurance or other remedy is not obtained and subject to such Investor's compliance with the preceding sentence, such Investor (1) may disclose such information only to the extent legally required based on the advice of such Investor's counsel, (2) will use reasonable best efforts, at such Investor's sole cost and expense, to obtain assurance that confidential treatment will be accorded to such information, (3) will give advance notice to the Company of the information to be disclosed, or the proposed disclosure itself (as applicable, as far in advance as practicable and (4) in the case of any required public disclosure, will give the Company a reasonable opportunity to comment on such disclosure prior to it being made public. Each Investor agrees that it will be liable for any breach of this Section 3.4 (*Confidentiality*) by any Person to whom it discloses confidential information pursuant to the foregoing clauses (i), (ii), and (iii). The obligations under this Section 3.4 (*Confidentiality*) shall survive the termination of this Agreement.

ARTICLE IV
RIGHT TO FUTURE SHARE ISSUANCES

Section 4.1 Right of First Offer. Subject to the terms and conditions of this Section 4.1 (*Right of First Offer*) and applicable Laws and Orders, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Investor. An Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates; provided that each such Affiliate agrees to enter into this Agreement and the Voting Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an “**Investor**” in each such agreement.

(a) The Company shall give notice (the “**Offer Notice**”) to each Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within [***] after the Offer Notice is given, each Investor may irrevocably elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Equity Securities then Beneficially Owned by such Investor and its Designated Affiliates (including all Equity Securities then issuable (directly or indirectly) upon conversion or exercise, as applicable, of any other Equity Securities then held by such Investor) bears to the total Equity Securities of the Company then outstanding (assuming full conversion or exercise, as applicable, of all other Equity Securities then outstanding) (with respect to each Investor, the “**Proportionate Percentage**”); provided, however, that an Investor’s election to purchase or acquire New Securities may be revoked in the event (i) any of the terms set forth in the Offer Notice are changed or (ii) any material term that had not been set forth in the Offer Notice is required or included in connection with such Investor’s purchase or acquisition of such New Securities. The closing of any sale pursuant to this Section 4.1(b) (*Right of First Offer*) shall occur within the later of [***] of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Section 4.1(c) (*Right of First Offer*); provided, however, that if such sale pursuant to this Section 4.1(b) would require the approval of any Governmental Authority prior to consummating such sale, such closing shall be extended to the date that is [***] after such approval has been obtained or finally denied, but in no event later than [***] after the Offer Notice is given.

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Section 4.1(b) (*Right of First Offer*), the Company may, during the [***] period following the expiration of the periods provided in Section 4.1(b) (*Right of First Offer*), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms not materially more favorable in the aggregate to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Section 4.1 (*Right of First Offer*).

(d) The right of first offer in this Section 4.1 (*Right of First Offer*) shall not be applicable to issuances of: (i) Exempted Securities; and (ii) securities issued in a Qualified Listing Event or to a new holding company solely for the purposes of a forthcoming Qualified Listing Event. In addition to the foregoing, the right of first offer in this Section 4.1 (*Right of First Offer*) shall not be applicable with respect to any particular Investor in any subsequent offering or sale of New Securities if (x) at the time of such offering or sale, such Investor is neither a “qualified institutional buyer” as that term is defined in Rule 144A under the Securities Act nor an “accredited investor” as that term is defined in Rule 501(a) of the Securities Act and (y) such offering or sale of Shares is otherwise being offered or made only to qualified institutional buyers or accredited investors, as the case may be.

(e) Notwithstanding anything to the contrary contained herein, in lieu of complying with the provisions of this Section 4.1 (*Right of First Offer*), the Company may consummate the offering and sale of New Securities without first providing an Offer Notice pursuant to Section 4.1(b) (*Right of First Offer*), provided that the Company complies with the terms and conditions of this Section 4.1(e) (*Right of First Offer*). In the event that an offering or sale of New Securities is consummated without prior delivery of an Offer Notice to one or more Investors, the Company shall, within [***] from the closing of such offer and sale of New Securities, provide each non-participating Investor with written notice of such offering (including the material terms and conditions thereof) and thereupon provide each such Investor with the right, which shall be exercisable for a period of [***] from delivery of such notice, to subscribe for a number of New Securities equal to such Investor’s Proportionate Percentage (calculated pursuant to Section 4.1(b) (*Right of First Offer*) before giving effect to the issuance of the New Securities) of the shares offered and sold in such offering, at the same price and on the same terms and conditions as which such securities were first sold. The closing of such sale shall occur within [***] of the date the notice is given to the Investor.

Section 4.2 Termination. The covenants set forth in Section 4.1 (*Right of First Offer*) shall terminate and be of no further force or effect upon the earliest of: (i) immediately before the consummation of a Qualified Listing Event (ii) the consummation of a Change of Control of the Company or (iii) the liquidation, winding up or other dissolution of the Company.

ARTICLE V ADDITIONAL COVENANTS

Section 5.1 Protective Provisions.

[***]

Section 5.2 Indemnification Matters. The Company hereby acknowledges that one (1) or more of the Preferred Directors nominated to serve on the Board by one (1) or more Investors may have certain rights to indemnification, advancement of expenses or insurance provided by one (1) or more of the Investors and certain of their Affiliates (collectively, the “**Investor Indemnitors**”). The Company hereby agrees (a) that it is the indemnitor of first resort (*i.e.*, its obligations to any such Preferred Director are primary and any obligation of the Investor Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Preferred Director are secondary), (b) that it shall be required to advance the full amount of expenses incurred by such Preferred Director and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement by or on behalf of any such Preferred Director to the extent legally permitted and as required by the Certificate of Incorporation or bylaws of the Company (or any agreement between the Company and such Preferred Director), without regard to any rights such Preferred Director may have against the Investor Indemnitors, and, (c) that it irrevocably waives, relinquishes and releases the Investor Indemnitors from any and all claims against the Investor Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Investor Indemnitors on behalf of any such Preferred Director with respect to any claim for which such Preferred Director has sought indemnification from the Company shall affect the foregoing and the Investor Indemnitors shall have a right of contribution or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Preferred Director against the Company. The Preferred Directors and the Investor Indemnitors are intended third-party beneficiaries of this Section 5.2 (*Indemnification Matters*) and shall have the right, power and authority to enforce the provisions of this Section 5.2 (*Indemnification Matters*) as though they were a party to this Agreement.

Section 5.3 [*]**

Section 5.4 Termination. The covenants set forth in Section 5.1 (*Protective Provisions*), [***], Section 5.9 (Board Matters), and [***] shall terminate and be of no further force or effect upon the earliest of: (i) immediately before the consummation of a Qualified Listing Event, (ii) the consummation of a Change of Control or (iii) the liquidation, winding up or other dissolution of the Company.

Section 5.5 Legal Compliance.

(a) **Compliance with Law.** The Company shall, and shall cause its Subsidiaries to, comply in all material respects with all applicable Laws, including applicable Healthcare Laws and accepted pharmaceutical industry business practices governing product research and development, marketing, promotion, and sale, including with respect to product claims and restrictions on “off-label” promotion, interactions with healthcare professionals, and product pricing and price-reporting obligations.

(b) **Foreign Corrupt Practices Act.** The Company shall not, and shall not permit any of its subsidiaries and affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents (collectively, “**Representatives**”) to, promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, any non-U.S. government official, in each case, in violation of the U.S. Foreign Corrupt Practices Act (“**FCPA**”) or any other applicable anti-bribery or anti-corruption law. If applicable at any time, the Company shall, and shall cause each of its subsidiaries and affiliates to, cease all of its or their respective activities, as well as remediate any actions taken by the Company, its subsidiaries or affiliates or any of its or their respective Representatives in violation of the FCPA or any other applicable anti-bribery or anti-corruption law. Within a reasonable period of time following the Closing (but in no event greater than six months post-Closing), the Company shall, and shall cause each of its affiliates to, institute and maintain a customary code of conduct and anti-corruption policy and commence devising applicable systems of internal controls (including, but not limited to, appropriate accounting systems, purchasing systems and billing systems, if reasonably necessary) to provide reasonable assurance that the Company and its affiliates will comply with the FCPA or any other applicable anti-bribery or anti-corruption law to the extent required by such laws. The Company will monitor its operations and the operations of each of its affiliates with the purpose of ensuring the systems and controls are effective at the reasonable assurance level and make necessary changes from time to time, in particular as its business activities expand. Solely for purposes of this Section 5.5(b) (*Foreign Corrupt Practices Act*), the term “affiliate” shall mean, with respect to a Person, any wholly or partially-owned subsidiary of such Person that the Person has the power to control.

(c) Global Trade Controls Compliance Program. For so long as the holders of record of Series A-2 Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation, the Series A-2 Preferred Director, the Company shall, and shall cause its Subsidiaries to, comply with Global Trade Control Laws, and will engage in activities involving Restricted Parties and Restricted Markets only as authorized by applicable Law.

Section 5.6 D&O Insurance. The Company shall use its best efforts to obtain and maintain in full force and effect directors and officers insurance in the amount of at least [***] for so long as human trials are not being conducted by the Company and its subsidiaries, and at least [***] once human trials are to be conducted by the Company or any of its subsidiaries, on such other terms as reasonably determined by the Board and covering such risks as are adequate and customary for its size and business, each with financially sound and reputable insurance companies or associations.

Section 5.7 [*]**

Section 5.8 [*]**

Section 5.9 Board Matters. The Company shall reimburse its nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board.

Section 5.10 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board as in effect immediately before such transaction, whether such obligations are contained in the Company's bylaws, the Certificate of Incorporation, or elsewhere, as the case may be.

Section 5.11 Right to Conduct Activities.

Section 5.12 [*]**

Section 5.13 Publicity.

(a) Subject to Pfizer's rights pursuant to Section 15.4.3(c)(iv) of the License Agreement, no Party (nor any of its Affiliates or agents) shall use the registered or unregistered trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance; provided, however, that the Company and any of its Affiliates or sublicensees may state publicly that Licensee (as defined in the License Agreement) has received, or been sublicensed under, a license from Pfizer to Exploit the Compounds and Products (each as defined in the License Agreement).

(b) The Parties acknowledge that one or more Parties, either singly or jointly, may desire to publish one or more press releases relating to the Transaction Documents, the rights granted thereunder, and developments made thereto. However, each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of the Transaction Documents, the terms hereof or thereof or any information relating to the Transaction Documents without the prior written consent of the other Parties, such consent not to be unreasonably withheld, conditioned or delayed; provided that a Party desiring to make such public disclosure may issue such press release or public announcement without such prior written consent by the other Party if (a) the entire contents of such press release or public announcement have previously been made public other than through a breach of the Transaction Documents by such Party, and (b) such press release or public announcement does not materially differ from a previously issued press release or other publicly available information. No Party will be prevented from complying with any duty of disclosure it may have pursuant to applicable Law or the rules of any recognized stock exchange so long as the disclosing Party provides the other Parties at least [***] prior written notice to the extent practicable and only discloses information to the extent required by applicable Law or the rules of any recognized stock exchange.

(c) The Parties acknowledge that nothing herein shall restrict disclosure and publication explicitly permitted pursuant to Section 16.3 of the License Agreement.

Section 5.14 [*]**

**ARTICLE VI
MISCELLANEOUS.**

Section 6.1 Successors and Assigns; Third Party Beneficiaries. No Investor shall assign its rights under this Agreement without the Company's prior written consent, except by a Holder to a transferee of Registrable Securities in accordance with this Agreement, or as otherwise expressly permitted by the terms hereof: (x) that is a Designated Affiliate of such Holder or (y) in connection with the Transfer of all Registrable Securities held by such Holder to such transferee; provided that: (i) such Transfer or assignment may otherwise be effected in accordance with applicable Laws and Orders, (ii) the Company is, within two (2) Business Days after such Transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (iii) such transferee agrees in a written instrument, in form and substance satisfactory to the Company, delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Section 2.11 ("*Market Stand-off*" Agreement); and provided further that, for the avoidance of doubt, in no case shall any Investor assign its rights under Section 5.1 (*Protective Provisions*) of this Agreement pursuant to the preceding clause (y) without the Company's prior written consent. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the Parties. Nothing in this Agreement, express or implied, is intended to confer upon any Party other than the Parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

Section 6.2 Governing Law; Dispute Resolution.

(a) This Agreement shall be governed and construed in all respects in accordance with the internal law of the State of Delaware, as such laws are applied to agreements among Delaware residents entered into and performed entirely within the state of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware.

(b) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or action arising from or related to this Agreement or the breach thereof. In the event that the Parties cannot resolve such dispute, controversy or action within a period of [***] from when the dispute, controversy or action is first identified in writing by the Party raising or asserting such dispute, controversy or action, then the matter shall be referred to designated representatives of the Parties for resolution by the sending of a notice of dispute(s) (a “**Notice of Dispute(s)**”). The designated representatives shall endeavor to meet in person or by means of telephone conference, video conference or similar communications equipment by means of which all Persons participating in the meeting can hear and speak to each other, and where such participation by the Parties’ designated representatives shall constitute presence in person at the meeting, within [***] following transmittal of the Notice of Dispute(s). Each Party shall be entitled to name representatives upon written notice to the other Party. The foregoing duties may be delegated to the extent the person delegated with such duties is duly authorized to enter into the foregoing resolution without seeking any additional approval within the respective Party.

(c) If the Parties do not fully settle any dispute, controversy or action referred to the representatives of the Parties within [***] of it being referred to them, and a Party wishes to pursue the matter, then such dispute, controversy or action shall be finally resolved by binding arbitration administered by the American Arbitration Association (“AAA”) pursuant to AAA’s Commercial Arbitration Rules then in effect.

(d) The arbitration shall be conducted by a panel of three (3) neutral arbitrators, each of whom shall have significant legal or business experience in the pharmaceutical industry, and none of whom shall be a current or former employee or director, or a current significant shareholder, of either Party or any of their respective Affiliates or sublicensees; and within [***] after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within [***] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, then on the [***] after the initiation of arbitration, the two (2) Party-selected arbitrators shall make a written request to AAA to appoint a third (3rd) arbitrator. AAA shall appoint such third (3rd) arbitrator within [***] of being notified by the two (2) Party-selected arbitrators. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(e) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party has the right to file an early dispositive motion seeking a determination on the issue of whether a material breach has occurred, and the arbitrators will promptly rule on such motion. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.

(f) Except to the extent necessary to confirm or enforce an award or as may be required by applicable Law, neither Party nor an arbitrator may disclose the existence, content or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable action based on the dispute, controversy or action would be barred by the applicable statute of limitations in the state of Delaware.

Section 6.3 Specific Performance. Each Party agrees that irreparable damage for which monetary relief, even if available, would not be an adequate remedy, would occur in the event that any provision of this Agreement is not performed in accordance with its specific terms or is otherwise breached. Each Party acknowledges and agrees that, notwithstanding Section 6.2 (*Governing Law; Dispute Resolution*), and without waiving any other remedy under this Agreement, the Parties shall be entitled to an injunction or injunctions, specific performance or other equitable relief from any court of competent jurisdiction to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof. The Parties agree not to assert that a remedy of specific enforcement or other equitable relief is unenforceable, invalid, contrary to Law or inequitable for any reason, and agree not to assert that a remedy of monetary damages would provide an adequate remedy or that the Parties otherwise have an adequate remedy at Law. The Parties acknowledge and agree that any Party seeking an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in accordance with this Section 6.3 (*Specific Performance*) shall not be required to provide any bond or other security in connection with any such injunction.

Section 6.4 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

Section 6.5 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

Section 6.6 Interpretation. Unless the context requires otherwise, (i) “include,” “includes” or “including” shall be deemed to be followed by “without limitation”; (ii) “hereof,” “herein,” “hereby,” “hereto” and “hereunder” shall refer to this Agreement as a whole and not to any particular provision of this Agreement; (iii) “extent” in the phrase “to the extent” shall mean the degree to which a subject or other item extends and shall not simply mean “if”; (iv) the singular includes the plural and vice versa; (v) “any” shall mean “any and all”; (vi) “or” is used in the inclusive sense of “and/or”; (vii) any reference to any Contract, Law or Order is a reference to it as amended, modified and supplemented from time to time (and, in the case of a Law, to (x) any successor provision and (y) the rules and regulations promulgated thereunder); (viii) the words “date hereof” shall refer to the date of this Agreement; (ix) any provision that requires action by a Series A-2 Preferred Director shall be applicable only so long as the Board includes a Series A-2 Preferred Director; and (x) all references to “\$” mean the lawful currency of the United States of America.

Section 6.7 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (a) personal delivery to the Party to be notified; (b) when sent, if sent by electronic mail during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next Business Day; (c) [***] after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) [***] after the Business Day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the Investors at their respective addresses set forth on Schedule 1 and to the Company at the address set forth on the signature pages hereto, or at such other address as the Company or the Investors may designate by [***] advance written notice to each other Party.

Section 6.8 Amendments and Waivers. Subject to the terms of this Section 6.8 (*Amendments and Waivers*), any term of this Agreement may be amended, modified or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of at least a majority of the Registrable Securities then outstanding; provided, however, that the Company may in its sole discretion: (a) add any holder of Shares or New Securities as an "**Investor**" and include such shares and securities as Registrable Securities, and (b) waive compliance with any obligation owed to the Company under Section 2.12(c) (*Restrictions on Transfer*) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Section 2.12(c) (*Restrictions on Transfer*) shall be deemed to be a waiver); and provided further that any provision hereof may be waived by any waiving Party on such Party's own behalf, without the consent of any other Party. Notwithstanding the foregoing:

(1) this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion;

[***]

Any amendment, termination, or waiver effected in accordance with this Section 6.8 (*Amendments and Waivers*) shall be binding on all Parties hereto, regardless of whether any such Party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

Section 6.9 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by applicable Law.

Section 6.10 Aggregation of Securities. All Registrable Securities held or acquired by Designated Affiliates of a Person shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Designated Affiliates may apportion such rights as among themselves in any manner they deem appropriate.

Section 6.11 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto), along with the Stock Purchase Agreement and other Transaction Documents, constitute the full and entire understanding and agreement among the Parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the Parties is expressly canceled.

Section 6.12 WAIVER OF JURY TRIAL. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

Section 6.13 Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any Party under this Agreement, upon any breach or default of any other Party under this Agreement, shall impair any such right, power or remedy of such non-breaching or non-defaulting Party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any Party of any breach or default under this Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by Law or otherwise afforded to any Party, shall be cumulative and not alternative

Section 6.14 Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional Equity Securities after the date hereof, then, at the Company's election, any purchaser of such securities may become a Party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement and thereafter shall be deemed an "**Investor**" for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an "**Investor**" hereunder.

Section 6.15 Business Day Requirements. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

[Signatures Follow]

IN WITNESS WHEREOF, the Parties have executed this Investor Rights Agreement as of the date first set forth above.

[***]

By [***]

Name: [***]

Title: [***]

IN WITNESS WHEREOF, the Parties have executed this Investor Rights Agreement as of the date first set forth above.

ROIIVANT SCIENCES LTD.

By [***]

Name: [***]

Title: [***]

IN WITNESS WHEREOF, the Parties have executed this Investor Rights Agreement as of the date first set forth above.

PFIZER INC.

By [***]

Name: [***]

Title: [***]

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 13, 2023

/S/ MATTHEW GLINE

Matthew Gline
Principal Executive Officer

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 13, 2023

/S/ RICHARD PULIK

Richard Pulik
Principal Financial Officer

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, 2022, 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 13, 2023

/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.

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, 2022, 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 13, 2023

/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.