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 September 30, 2023
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	**98-1173944**
(State or other jurisdiction of incorporation or organization)	**(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Market**

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.

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

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

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

As of November 9, 2023, the registrant had 803,921,356 common shares, par value $0.0000000341740141 per share, outstanding (the "Common Shares").

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Where You Can Find More Information

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (https://investor.roivant.com), filings we make with the Securities and Exchange Commission (the "SEC"), our corporate twitter account (@Roivant), other social media platforms, webcasts, press releases and conference calls. Similarly, our subsidiary Immunovant, Inc. may announce material business and financial information to its investors and others 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 have not generated significant revenue from our operations since inception, and there is no guarantee that we will do so in the future.
- 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.
- We may not be successful in our efforts to acquire or in-license new product candidates.
- Our drug discovery efforts may not be successful in identifying 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.
- We face risks associated with potential future payments related to our products and product candidates.
- We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.
- 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.
- 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.
- We may encounter difficulties enrolling and retaining patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.
- The results of our preclinical studies and clinical trials may not support our proposed claims for our products or product candidates, or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

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

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

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

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

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

- 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. Any such outcome could have a materially adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications.

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

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

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

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

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

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

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

Forward-Looking Statements

This 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 fact that we will likely incur significant operating losses for the foreseeable future;
- our ability to acquire or in-license new product candidates;
- our ability to identify new product candidates through our discovery efforts;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- our ability to consummate strategic transactions, including the Roche Transaction (as defined below);
- 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;
- clinical trials and preclinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- the novelty, complexity and difficulty of manufacturing certain of our products and product candidates, including any manufacturing problems that result in delays in development or commercialization of our products and product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials 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 own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval;
- future sales of securities by us or our largest shareholders, or the perception of such sales, and the impact thereof on the price of our common shares;
- the outcome of any pending or potential litigation, including but not limited to our expectations regarding the outcome of any such litigation and costs and expenses associated with such litigation;
- changes in applicable laws or regulations;
- the possibility that we may be adversely affected by other economic, business and/or competitive factors; and
- any other risks and uncertainties, including those described under Part 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)

	September 30, 2023	March 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,408,231	$ 1,676,813
Other current assets	143,396	121,774
Total current assets	1,551,627	1,798,587
Property and equipment, net	24,477	39,086
Operating lease right-of-use assets	48,629	53,251
Investments measured at fair value	250,393	304,317
Intangible assets, net	140,621	144,881
Other assets	49,796	49,482
Total assets	$ 2,065,543	$ 2,389,604
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 44,123	$ 37,830
Accrued expenses	152,923	167,129
Operating lease liabilities	10,903	11,693
Current portion of long-term debt (includes $28,120 and $26,940 accounted for under the fair value option at September 30, 2023 and March 31, 2023, respectively)	48,998	40,720
Other current liabilities	8,599	15,076
Total current liabilities	265,546	272,448
Liability instruments measured at fair value	31,114	63,546
Operating lease liabilities, noncurrent	48,630	53,476
Long-term debt, net of current portion (includes $188,911 and $180,700 accounted for under the fair value option at September 30, 2023 and March 31, 2023, respectively)	389,445	375,515
Other liabilities	5,175	17,032
Total liabilities	739,910	782,017
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 800,792,365 and 760,143,393 shares issued and outstanding at September 30, 2023 and March 31, 2023, respectively	—	—
Additional paid-in capital	5,320,503	4,933,137
Accumulated deficit	(4,368,897)	(3,772,754)
Accumulated other comprehensive loss	(3,072)	(2,617)
Shareholders' equity attributable to Roivant Sciences Ltd.	948,534	1,157,766
Noncontrolling interests	377,099	449,821
Total shareholders' equity	1,325,633	1,607,587
Total liabilities and shareholders' equity	$ 2,065,543	$ 2,389,604

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

ROIVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 18,424	$ 4,969	$ 35,083	$ 5,110
License, milestone and other revenue	18,677	7,564	23,642	11,742
Revenue, net	37,101	12,533	58,725	16,852
Operating expenses:				
Cost of revenues	3,266	3,641	7,480	5,367
Research and development (includes $8,877 and $7,417 of share-based compensation expense for the three months ended September 30, 2023 and 2022 and $16,830 and $19,660 for the six months ended September 30, 2023 and 2022, respectively)	131,984	131,995	257,117	267,825
Acquired in-process research and development	13,950	—	26,450	—
Selling, general and administrative (includes $40,309 and $54,479 of share-based compensation expense for the three months ended September 30, 2023 and 2022 and $81,501 and $115,030 for the six months ended September 30, 2023 and 2022, respectively)	164,355	157,663	320,545	306,735
Total operating expenses	313,555	293,299	611,592	579,927
Loss from operations	(276,454)	(280,766)	(552,867)	(563,075)
Change in fair value of investments	45,849	54,678	53,413	79,225
Change in fair value of debt and liability instruments	21,533	(13,541)	76,045	27,672
Gain on deconsolidation of subsidiaries	(17,354)	(16,762)	(17,354)	(16,762)
Interest income	(14,299)	(5,670)	(31,014)	(7,651)
Interest expense	9,247	8,335	18,159	10,947
Other expense, net	5,931	5,950	1,338	7,035
Loss before income taxes	(327,361)	(313,756)	(653,454)	(663,541)
Income tax expense	3,757	2,165	5,509	6,164
Net loss	(331,118)	(315,921)	(658,963)	(669,705)
Net loss attributable to noncontrolling interests	(26,791)	(24,331)	(62,820)	(46,306)
Net loss attributable to Roivant Sciences Ltd.	$ (304,327)	$ (291,590)	$ (596,143)	$ (623,399)
Net loss per common share—basic and diluted	$ (0.40)	$ (0.42)	$ (0.78)	$ (0.89)
Weighted average shares outstanding—basic and diluted	770,227,849	699,888,061	764,780,630	697,894,414

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

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (331,118)	$ (315,921)	$ (658,963)	$ (669,705)
Other comprehensive income (loss):				
Foreign currency translation adjustment	3,602	3,752	(546)	9,519
Total other comprehensive income (loss)	3,602	3,752	(546)	9,519
Comprehensive loss	(327,516)	(312,169)	(659,509)	(660,186)
Comprehensive loss attributable to noncontrolling interests	(26,727)	(24,648)	(62,911)	(46,822)
Comprehensive loss attributable to Roivant Sciences Ltd.	$ (300,789)	$ (287,521)	$ (596,598)	$ (613,364)

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						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2023	**760,143,393**	**$ —**	**$ 4,933,137**	**$ (2,617)**	**$ (3,772,754)**	**$ 449,821**	**$ 1,607,587**
Issuance of the Company's common shares in connection with equity incentive plans and tax withholding payments	6,994,468	—	14,395	—	—	—	14,395
Subsidiary stock options exercised	—	—	503	—	—	387	890
Cash contributions to majority-owned subsidiaries	—	—	(623)	—	—	623	—
Dividend declared by subsidiary	—	—	—	—	—	(6,000)	(6,000)
Share-based compensation	—	—	34,498	—	—	14,762	49,260
Foreign currency translation adjustment	—	—	—	(3,993)	—	(155)	(4,148)
Net loss	—	—	—	—	(291,816)	(36,029)	(327,845)
Balance at June 30, 2023	**767,137,861**	**$ —**	**$ 4,981,910**	**$ (6,610)**	**$ (4,064,570)**	**$ 423,409**	**$ 1,334,139**
Issuance of the Company's common shares, net of issuance costs	19,600,685	—	199,822	—	—	—	199,822
Issuance of the Company's common shares related to settlement of warrants	7,554,549	—	83,264	—	—	—	83,264
Issuance of the Company's common shares under employee stock purchase plan	96,385	—	587	—	—	—	587
Issuance of the Company's common shares in connection with equity incentive plans, net of forfeitures, and tax withholding payments	6,402,885	—	20,873	—	—	—	20,873
Deconsolidation of subsidiaries	—	—	—	—	—	(35,050)	(35,050)
Subsidiary stock options exercised	—	—	131	—	—	65	196
Cash contributions to majority-owned subsidiaries	—	—	(571)	—	—	571	—
Share-based compensation	—	—	34,487	—	—	14,831	49,318
Foreign currency translation adjustment	—	—	—	3,538	—	64	3,602
Net loss	—	—	—	—	(304,327)	(26,791)	(331,118)
Balance at September 30, 2023	**800,792,365**	**$ —**	**$ 5,320,503**	**$ (3,072)**	**$ (4,368,897)**	**$ 377,099**	**$ 1,325,633**

	Redeemable Noncontrolling Interest	Shareholders' Equity						
		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount					
Balance at March 31, 2022	**$ 22,491**	**694,975,965**	**$ —**	**$ 4,421,614**	**$ (946)**	**$ (2,763,724)**	**$ 381,999**	**$ 2,038,943**
Issuance of subsidiary common shares to the Company	—	—	—	(251)	—	—	251	—
Issuance of the Company's 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 the Company's 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
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	—	(2,240)	—	—	2,240	—
Deconsolidation of subsidiary	(22,491)	—	—	—	—	—	—	—
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**

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

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

	Six Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (658,963)	$ (669,705)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	98,578	134,773
Change in fair value of investments	53,413	79,225
Change in fair value of debt and liability instruments	76,045	27,672
Gain on deconsolidation of subsidiaries	(17,354)	(16,762)
Depreciation and amortization	11,426	7,753
Non-cash lease expense	3,316	4,194
Other	5,295	8,716
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Other current assets	(26,279)	(30,219)
Accounts payable	10,142	6,774
Accrued expenses	(12,390)	1,447
Operating lease liabilities	(4,154)	(4,753)
Other	14,566	9,173
Net cash used in operating activities	(446,359)	(441,712)
Cash flows from investing activities:		
Milestone payments	—	(140,136)
Purchase of property and equipment	(678)	(10,560)
Proceeds from sale of subsidiary interests	47,500	—
Cash decrease upon deconsolidation of subsidiaries	(83,679)	(3,615)
Other	511	—
Net cash used in investing activities	(36,346)	(154,311)
Cash flows from financing activities:		
Proceeds from issuance of the Company's common shares, net of issuance costs paid	199,822	—
Proceeds from subsidiary debt financings, net of financing costs paid	—	159,899
Payment of subsidiary dividend	(6,000)	—
Repayment of debt by subsidiary	(14,471)	(14,685)
Payment of offering costs and loan origination costs	—	(2,250)
Payments on principal portion of finance lease obligations	(907)	—
Proceeds from exercise of the Company's and subsidiary stock options	42,142	—
Taxes paid related to net settlement of equity awards	(5,788)	(8,329)
Proceeds from issuance of the Company's common shares under employee stock purchase plan	587	—
Proceeds from exercise of the Company's warrants	5	—
Payment for redemptions of the Company's warrants	(41)	—
Net cash provided by financing activities	215,349	134,635
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(1,571)	—
Net change in cash, cash equivalents and restricted cash	(268,927)	(461,388)
Cash, cash equivalents and restricted cash at beginning of period	1,692,115	2,074,034
Cash, cash equivalents and restricted cash at end of period	$ 1,423,188	$ 1,612,646
Non-cash investing and financing activities:		
Cashless exercise of the Company's warrants	$ 83,258	$ —
Issuance of the Company's common shares and other consideration for an acquisition	$ —	$ 9,694
Other	$ 33	$ 691

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, "Equity Method 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 September 30, 2023, the Company had cash and cash equivalents of approximately $1.4 billion and its accumulated deficit was approximately $4.4 billion. For the six months ended September 30, 2023 and 2022, the Company incurred net losses of approximately $659.0 million and $669.7 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, 2023 filed with the SEC. The unaudited condensed consolidated balance sheet at March 31, 2023 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 six months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2024, 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.

(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 September 30, 2023 and March 31, 2023, 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.

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):

	September 30, 2023	March 31, 2023
Cash and cash equivalents	$ 1,408,231	$ 1,676,813
Restricted cash (included in “Other current assets”)	5,474	5,011
Restricted cash (included in “Other assets”)	9,483	10,291
Cash, cash equivalents and restricted cash	$ 1,423,188	$ 1,692,115

(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) 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, “Equity Method Investments.”

(G) 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 Heracles Parent, L.L.C., the parent entity of Datavant, (as defined and discussed in Note 3, "Equity Method Investments"); liability instruments issued, including warrant and earn-out shares liabilities issued in connection with the Company's business combination with MAAC (as discussed in 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 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, "Equity Method 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. Prior to their settlement, the Public Warrants were publicly traded and therefore were classified as Level 1 as the Public Warrants had a readily determinable fair value. Cash and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant 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.

(H) Significant Accounting Policies

There were no significant changes to the Company's significant accounting policies from those disclosed in the Company's Form 10-K for the year ended March 31, 2023.

(I) Recently Adopted Accounting Pronouncements

The Company did not adopt any material accounting pronouncements during the six months ended September 30, 2023.

(J) Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise disclosed above, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its condensed consolidated financial statements and disclosures.

Note 3—Equity Method Investments

The Company maintains equity method investments in certain entities. As of September 30, 2023 and March 31, 2023, the most significant of these were our investments in Arbutus and Datavant, which are accounted for using the fair value option.

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

Investment in Arbutus

The Company holds an investment in Arbutus in the form of 38,847,462 common shares of Arbutus. As of September 30, 2023, RSL held approximately 23% of issued and outstanding shares of Arbutus.

At September 30, 2023 and March 31, 2023, the aggregate fair value of the Company's investment in Arbutus was $78.9 million and $117.7 million, respectively. During the three and six months ended September 30, 2023, the Company recognized unrealized losses of $10.5 million and $38.8 million on its investment in Arbutus, respectively, in the accompanying condensed consolidated statements of operations. During the three and six months ended September 30, 2022, the Company recognized unrealized losses of $31.1 million and $41.6 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 September 30, 2023 and March 31, 2023 of $2.03 and $3.03, respectively.

Investment in Datavant

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"), 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"). As of September 30, 2023, 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 rights. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted.

As of September 30, 2023 and March 31, 2023, the fair value of the Company's investment was $164.3 million and $178.6 million, respectively. During the three and six months ended September 30, 2023, the Company recognized unrealized losses on its investment in Datavant of $35.1 million and $14.3 million, respectively, in the accompanying condensed consolidated statements of operations. During the three and six months ended September 30, 2022, the Company recognized unrealized losses on its investment of $21.9 million and $28.9 million, respectively, in the accompanying condensed consolidated statements of operations.

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

Following the FDA approval of VTAMA in May 2022, the Company became obligated to pay a regulatory milestone to GSK of £100.0 million (approximately $126 million on the date of achievement) following the receipt of marketing approval of VTAMA in the 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 Welichem Biotech Inc. of CAD$25.0 million (approximately $20 million on the date of achievement). The milestone was paid in August 2022.

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

The following table summarizes the Company's recognized intangible assets:

	Remaining Weighted Average Estimated Useful Lives (in years)	September 30, 2023 (in thousands)
Gross amount	15.0	$ 153,052
Less: accumulated amortization		(12,431)
Net book value		$ 140,621

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 $2.4 million and $2.2 million for the three months ended September 30, 2023 and 2022, respectively, and $4.8 million and $2.9 million for the six months ended September 30, 2023 and 2022, respectively. Amortization expense was recorded as part of "Cost of revenues" in the accompanying condensed consolidated statement of operations. Future amortization expense is approximately $4.7 million for the remainder of the year ended March 31, 2024, $9.3 million for each of the years ended from March 31, 2025 through March 31, 2028 and $98.7 million thereafter.

Note 5—Recent Transactions

(A) Asset Acquisition

In July 2023, a newly-formed subsidiary in-licensed certain intellectual property rights in exchange for a $14.0 million upfront cash payment. The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The acquired rights represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded $14.0 million as acquired in-process research and development expense in the accompanying condensed consolidated statements of operations for the three and six months ended September 30, 2023.

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

(B) Deconsolidation of Subsidiaries

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

As a result of changes in governance and voting rights, the Company determined that it no longer held a controlling financial interest in VantAI. Accordingly, the Company deconsolidated VantAI as of July 2023. The Company recorded a $17.4 million gain on deconsolidation of Proteovant and VantAI in the accompanying condensed consolidated statements of operations for the three and six months ended September 30, 2023.

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

Note 6—Certain Balance Sheet Components

(A) Other Current Assets

Other current assets at September 30, 2023 and March 31, 2023 consisted of the following (in thousands):

	September 30, 2023	March 31, 2023
Prepaid expenses	$ 60,718	$ 60,827
Trade receivables, net	52,118	30,379
Restricted cash	5,474	5,011
Inventory	4,905	2,761
Income tax receivable	2,506	2,356
Other	17,675	20,440
Total other current assets	$ 143,396	$ 121,774

(B) Accrued Expenses

Accrued expenses at September 30, 2023 and March 31, 2023 consisted of the following (in thousands):

	September 30, 2023	March 31, 2023
Research and development expenses	$ 72,554	$ 76,278
Compensation-related expenses	30,723	55,186
Sales allowances	18,944	17,569
Other expenses	30,702	18,096
Total accrued expenses	$ 152,923	$ 167,129

(C) Other Current Liabilities

Other current liabilities at September 30, 2023 and March 31, 2023 consisted of the following (in thousands):

	September 30, 2023	March 31, 2023
Deferred revenue	$ 5,798	$ 12,444
Income tax payable	1,358	542
Other	1,443	2,090
Total other current liabilities	$ 8,599	$ 15,076

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 and has made cumulative quarterly payments totaling $44.1 million as of September 30, 2023.

At issuance, the Company concluded that certain features of the long-term debt would be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, the Company has elected the fair value option for this financial instrument and records the changes in the fair value within the statements of operations at the end of each reporting period. Direct costs and fees related to the debt issued under the NovaQuest Agreement were recognized in earnings. As of September 30, 2023 and March 31, 2023, the fair value of the debt was $217.0 million and $207.6 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 was as follows (in thousands):

	September 30, 2023	March 31, 2023
Fair value of long-term debt	$ 217,031	$ 207,640
Less: current portion	(28,120)	(26,940)
Total long-term debt, net	$ 188,911	$ 180,700

Credit Facility with XYQ Luxco

In May 2021, Dermavant and certain of its subsidiaries entered into a $40.0 million senior secured credit facility (the "Credit Facility") with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent. The Credit Facility has a five-year maturity and bears an interest rate of 10.0% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter through the maturity date. A lump sum principal payment is due on the maturity date. Dermavant is also obligated to pay an exit fee of $5.0 million. The exit fee can be reduced to $4.0 million upon achievement of certain equity milestones defined in the agreement, which are not deemed likely as of September 30, 2023. In connection with the funding of the Credit Facility, Dermavant issued a warrant to XYQ Luxco to purchase 1,199,072 common shares of Dermavant at an exercise price of $0.01 per common share.

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

	September 30, 2023	March 31, 2023
Principal amount	$ 40,000	$ 40,000
Exit fee	5,000	5,000
Less: unamortized discount and debt issuance costs	(8,905)	(10,170)
Total debt, net	36,095	34,830
Less: current portion	—	—
Total long-term debt, net	$ 36,095	$ 34,830

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 was as follows (in thousands):

	September 30, 2023	March 31, 2023
Carrying balance	$ 189,714	$ 178,571
Less: unamortized issuance costs	(4,397)	(4,806)
Total debt, net	185,317	173,765
Less: current portion	(20,878)	(13,780)
Total long-term debt, net	$ 164,439	$ 159,985

Note 8—Shareholders' Equity

(A) 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 September 30, 2023, the Company had $400.0 million of remaining capacity available under the ATM Facility.

(B) Common Share Purchase and Share Agreements

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

Note 9—Share-Based Compensation

(A) RSL Equity Incentive Plans

RSL has three equity incentive plans: the Roivant Sciences Ltd. 2021 Equity Incentive Plan (the "RSL 2021 EIP"), the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan, 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 September 30, 2023, a total of 41,722,310 common shares were available for future grants under the RSL 2021 EIP.

Stock Options and Performance Stock Options

Activity for stock options and performance stock options under the RSL Equity Plans for the six months ended September 30, 2023 was as follows:

	Number of Options
Options outstanding at March 31, 2023	154,271,791
Granted	4,497,911
Exercised	(9,411,537)
Forfeited/Canceled	(604,245)
Options outstanding at September 30, 2023	148,753,920
Options exercisable at September 30, 2023	86,575,431

Restricted Stock Units and Performance Stock Units

Activity for restricted stock units and performance stock units under the RSL Equity Plans for the six months ended September 30, 2023 was as follows:

	Number of Shares
Non-vested balance at March 31, 2023	20,700,788
Granted	4,123,913
Vested	(4,023,340)
Forfeited	(727,950)
Non-vested balance at September 30, 2023	20,073,411

Capped Value Appreciation Rights

March 2020 CVAR Grants

As of September 30, 2023, there were 591,887 non-service-vested capped value appreciation rights ("CVARs") and 28,161,790 service-vested CVARs relating to the March 2020 grants. During the six months ended September 30, 2023, 3,247,903 service-vested CVARs subject to the knock-in condition satisfied both the applicable hurdle price and the knock-in condition on the applicable measurement date, and as a result, 1,059,907 common shares were issued upon their settlement.

November 2021 CVAR Grants

Activity for CVARs under the RSL 2021 EIP for the six months ended September 30, 2023 was as follows:

	Number of CVARs
Non-vested balance at March 31, 2023	3,222,645
Vested	(628,971)
Forfeited	(87,175)
Non-vested balance at September 30, 2023	2,506,499

During the six months ended September 30, 2023, 628,971 common shares were issued upon their settlement.

(B) Subsidiary Equity Incentive Plans

Certain subsidiaries of RSL adopt their own equity incentive plan ("EIP"). Each EIP is generally structured so that the applicable subsidiary, and its affiliates' employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted stock unit awards, and other share awards under their respective EIP. The Company recorded share-based compensation expense of $14.9 million and $29.8 million for the three and six months ended September 30, 2023, respectively, and $12.6 million and $24.1 million for the three and six months ended September 30, 2022, respectively, related to subsidiary EIPs.

Note 10—Income Taxes

The Company's effective tax rate for the three and six months ended September 30, 2023 was (1.1)% and (0.8)%, respectively, and the effective tax rate for the three and six months ended September 30, 2022 was (0.7)% and (0.9)%, 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 Dermavant's entry into the GSK Agreement in 2018, Dermavant entered into a clinical supply agreement pursuant to which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during the Company's clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and 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 agreed to provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. As of September 30, 2023, the minimum purchase commitment related to these agreements is estimated to be approximately $42.6 million.

In November 2021, the Company's subsidiary, Immunovant, Inc. ("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 September 30, 2023, the minimum purchase commitment related to this agreement is estimated to be approximately $18.7 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 September 30, 2023, the remaining minimum payments for this software subscription are $19.1 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 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 leases during the six months ended September 30, 2023 outside the ordinary course of business. For further information regarding the Company's lease commitments, refer to Note 15, "Leases" in the Company's Annual Report on Form 10-K for the year ended March 31, 2023.

(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. In December 2021, the U.S. District Court appointed a lead plaintiff. In March 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. In February 2023, after further briefing on the amended complaint the U.S. District Court issued an order permitting the lead plaintiff to file a second amended complaint. That second amended complaint was filed in March 2023. The defendants' served motions to dismiss the second amended complaint on April 28, 2023. The fully briefed motions to dismiss, including defendants' opening briefs, lead plaintiff's opposition and defendants' replies, were filed with the court on June 30, 2023. No hearing date has yet 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. ("Acuitas") filed a lawsuit in the U.S. District Court for the Southern District of New York ("SDNY") against two of the Company's affiliates, Genevant and Arbutus, seeking a declaratory judgment that certain patents held by Arbutus and licensed by Genevant are not infringed by the manufacture, use, offer for sale, sale or importation into the 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, 2022, Genevant and Arbutus filed a motion to dismiss the first amended complaint for lack of a controversy and supporting brief. Briefing on this motion was completed in mid-November. On August 4, 2023, Acuitas voluntarily dismissed the action in the SDNY and re-filed a complaint in the U.S. District Court for the District of New Jersey. On October 13, 2023, Genevant and Arbutus filed a motion to dismiss the re-filed complaint. Each of Genevant and Arbutus intends 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 and officers. To date, the Company has not incurred any material costs related to these indemnification obligations and has not accrued any liabilities related to such obligations in the condensed consolidated financial statements as of September 30, 2023 and March 31, 2023.

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 statements of operations. As of September 30, 2023, no Earn-Out Shares have vested.

Public Warrants and Private Placement Warrants

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

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

Under the terms of the Warrant Agreement, the Company was entitled to redeem the Public Warrants at a redemption price of $0.10 per Public Warrant because the last reported sales price (the "Reference Value") of the Company's common shares was at least $10.00 per share for any twenty (20) trading days within the thirty (30) trading-day period ending on the third trading day prior to the date on which RSL gave a Notice of Redemption. In addition, because the Reference Value was less than $18.00 per share, the outstanding Private Placement Warrants were also required to be concurrently called for redemption on the same terms as the outstanding Public Warrants. This share price performance requirement was satisfied as of July 28, 2023. On August 2, 2023, the Company announced that it would redeem all Warrants that remain outstanding on September 1, 2023 (the "Redemption Date").

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

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

Note 13—Fair Value Measurements

Recurring Fair Value Measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2023 and March 31, 2023, by level, within the fair value hierarchy (in thousands):

	As of September 30, 2023				As of March 31, 2023			
	Level 1	Level 2	Level 3	Balance as of September 30, 2023	Level 1	Level 2	Level 3	Balance as of March 31, 2023
Assets:								
Money market funds	$ 995,030	$ —	$ —	$ 995,030	$ 1,496,726	$ —	$ —	$ 1,496,726
Investment in Datavant Class A units	—	—	164,325	164,325	—	—	178,579	178,579
Investment in Arbutus common shares	78,860	—	—	78,860	117,708	—	—	117,708
Other investments	7,208	—	—	7,208	8,030	—	—	8,030
Total assets at fair value	$ 1,081,098	$ —	$ 164,325	$ 1,245,423	$ 1,622,464	$ —	$ 178,579	$ 1,801,043
Liabilities:								
Debt issued by Dermavant to NovaQuest	$ —	$ —	$ 217,031	$ 217,031	$ —	$ —	$ 207,640	$ 207,640
Liability instruments measured at fair value[(1)]	—	—	31,114	31,114	29,895	—	33,651	63,546
Total liabilities at fair value	$ —	$ —	$ 248,145	$ 248,145	$ 29,895	$ —	$ 241,291	$ 271,186

(1) At September 30, 2023, Level 3 includes the fair value of the Earn-Out Shares of $27.6 million and other liability instruments issued of $3.5 million. At March 31, 2023, Level 1 includes the fair value of the Public Warrants of $29.9 million, and Level 3 includes the fair value of the Earn-Out Shares of $15.2 million, Private Placement Warrants of $15.2 million, and other liability instruments issued of $3.3 million.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the six months ended September 30, 2023.

Level 3 Disclosures

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

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

The changes in fair value of the Level 3 assets during the six months ended September 30, 2023 and 2022 were as follows (in thousands):

Balance at March 31, 2022	$ 193,963
Changes in fair value of investment in Datavant, included in net loss	(28,942)
Balance at September 30, 2022	$ 165,021

Balance at March 31, 2023	$ 178,579
Changes in fair value of investment in Datavant, included in net loss	(14,254)
Balance at September 30, 2023	$ 164,325

The changes in fair value of the Level 3 liabilities during the six months ended September 30, 2023 and 2022 were as follows (in thousands):

Balance at March 31, 2022	$ 204,293
Payments related to long-term debt	(14,687)
Changes in fair value of debt and liability instruments, included in net loss	37,705
Balance at September 30, 2022	$ 227,311

Balance at March 31, 2023	$ 241,291
Payments related to long-term debt	(14,687)
Exercise of Private Placement Warrants	(28,090)
Changes in fair value of debt and liability instruments, included in net loss	49,631
Balance at September 30, 2023	$ 248,145

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:

	Point Estimate Used	
Input	**As of September 30, 2023**	**As of March 31, 2023**
Volatility	100.0%	100.0%
Risk-free rate	5.07%	4.02%

Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of September 30, 2023 and March 31, 2023 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:

	Point Estimate Used	
Input	**As of September 30, 2023**	**As of March 31, 2023**
Volatility	69.3%	79.9%
Risk-free rate	4.80%	3.76%

As of September 30, 2023 and March 31, 2023, the fair value of the Earn-Out Shares was $27.6 million and $15.2 million, respectively. Earn-Out Shares were included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Private Placement Warrants

Prior to their settlement, the fair value of the Private Placement Warrants issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to incorporate the redemption features as discussed in Note 12, "Earn-Out Shares, Public Warrants and Private Placement Warrants" and the added restriction by which the Company could not redeem the Private Placement Warrants if the Reference Value was greater than $18.00. Significant unobservable inputs used to calculate the fair value of the Private Placement Warrants included the following:

	Point Estimate Used
Input	**As of March 31, 2023**
Volatility	50.5%
Risk-free rate	3.76%
Term (in years)	3.50

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

Note 14—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 September 30, 2023 and 2022, potentially dilutive securities were as follows:

	September 30, 2023	**September 30, 2022**
Stock options and performance stock options	148,753,920	154,836,057
Restricted stock units and performance stock units (non-vested)	20,073,411	25,214,766
March 2020 CVARs[(1)]	28,753,677	32,011,996
November 2021 CVARs (non-vested)	2,506,499	4,060,128
Restricted common stock (non-vested)	487,005	772,018
Earn-Out Shares (non-vested)	3,080,387	3,080,387
Private Placement Warrants	—	10,214,365
Public Warrants	—	20,475,875
Other stock based awards and instruments issued	5,611,820	6,209,162

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

Note 15—Subsequent Events

In October 2023, the Company's subsidiary, Immunovant, completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by the Company on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of $38.00 per share. Concurrent with the public offering, the Company purchased 4,473,684 shares of Immunovant's common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of $38.00 per share. The net proceeds to Immunovant were approximately $466.6 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses. The Company's participation in Immunovant's October offering resulted in an equity ownership interest in Immunovant of approximately 55%, and the Company will continue to consolidate Immunovant.

On October 22, 2023, the Company, the Company's subsidiary Telavant Holdings, Inc. ("Telavant"), Pfizer Inc. ("Pfizer") and Roche Holdings, Inc. ("Roche") entered into a Stock Purchase Agreement (the "Purchase Agreement"), pursuant to which Roche agreed to acquire all of the issued and outstanding shares of capital stock of Telavant on the terms and subject to the conditions set forth in the Purchase Agreement (the "Roche Transaction"). Telavant holds the rights to RVT-3101, an anti-TL1A antibody in development for ulcerative colitis ("UC") and Crohn's disease. The Company owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%, in each case on an as-converted basis.

The total consideration to be paid by Roche is comprised of (i) $7.1 billion in cash at the closing of the Roche Transaction, subject to certain customary adjustments as set forth in the Purchase Agreement, and (ii) a one-time milestone payment of $150 million in cash payable upon the initiation of a Phase 3 trial in UC, as described in more detail in the Purchase Agreement, in each case to be paid to all of Telavant's equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction. The Company expects to receive cash proceeds of approximately $5.2 billion upon closing of the Roche Transaction and is eligible to receive approximately $110 million for its portion of a one-time milestone payment upon Phase 3 initiation in UC.

The Company is in the process of evaluating the accounting impact on the consolidated financial statements. The Roche Transaction is expected to close in the fourth quarter of calendar year 2023 or the first quarter of calendar year 2024. The closing of the Roche Transaction is subject to the satisfaction or waiver of certain customary closing conditions, including certain regulatory approvals. The Purchase Agreement contains customary representations, warranties and covenants related to the Roche Transaction. The Purchase Agreement also includes customary termination provisions and provides that, if the Roche Transaction has not been consummated by July 23, 2024, the parties may terminate the Purchase Agreement and abandon the Roche Transaction.

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, 2023, included in our Annual Report on Form 10-K, filed with the SEC on June 28, 2023 (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

Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant's pipeline includes VTAMA, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several immunoglobulin G ("IgG") mediated autoimmune indications; brepocitinib, a novel TYK2/JAK1 inhibitor in late stage development for dermatomyositis, systemic lupus erythematosus and other autoimmune conditions; and additional clinical stage molecules. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business.

In October 2023, Roivant entered into a definitive agreement to sell its subsidiary, Telavant Holdings, Inc. ("Telavant"), to Roche Holdings, Inc. (the "Roche Transaction"). The agreement includes the development, manufacturing and commercialization rights in the United States and Japan for RVT-3101, a novel TL1A directed antibody, held by Telavant. The Roche Transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. The Roche Transaction is currently expected to close in the fourth quarter of calendar year 2023 or the first quarter of calendar year 2024.

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

Product/Product Candidate	Indication	Vant	Modality	Phase
VTAMA (tapinarof)	Psoriasis	Dermavant	Topical	Commercial
VTAMA (tapinarof)	Atopic Dermatitis	Dermavant	Topical	Phase 3 Completed*
RVT-3101	Ulcerative Colitis	Telavant	Biologic	Phase 3*+
RVT-3101	Crohn's Disease	Telavant	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
Namilumab	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.*

+ Subject to a definitive agreement to sell Telavant to Roche. For more information on the Roche Transaction, please refer to Note 15 to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of September 30, 2023.

	Roivant Ownership	
Vant	**Basic[1]**	**Fully Diluted[2]**
Dermavant	100%	85%
Immunovant	56%[3]	49%[3]
Telavant	75%†	74%†
Priovant	75%	68%
Genevant	83%	65%
Kinevant	96%	90%
Hemavant	100%	99%
Covant	100%	92%
Psivant	100%	87%
Arbutus	23%[3]	21%[3]
Lokavant	65%	56%
VantAI	60%	50%
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. Immediately following the closing of Immunovant's financing on October 2, 2023, Roivant held a 55% Basic and 49% Fully Diluted ownership interest in Immunovant.*

† *Subject to a definitive agreement to sell Telavant to Roche. For more information on the Roche Transaction, please refer to Note 15 to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.*

* *As of September 30, 2023, 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.*

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

Program	**Vant**	**Catalyst**	**Expected Timing**
VTAMA (tapinarof) cream	Dermavant	Updates on commercial launch of VTAMA in psoriasis	Ongoing
Roivant pipeline growth	Roivant	New mid/late-stage in-licensing announcements	Ongoing
LNP platform	Genevant	Updates to LNP patent litigation	Ongoing
IMVT-1402	Immunovant	Data from IMVT-1402 MAD 600mg SC cohort	Nov. 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	Year-end 2023
RVT-2001	Hemavant	Data from RVT-2001 Phase 1/2 trial in lower-risk myelodysplastic syndrome	1Q 2024
VTAMA (tapinarof) cream	Dermavant	Expected sNDA filing for VTAMA in atopic dermatitis	1Q 2024
Brepocitinib	Priovant	Topline data from proof-of-concept trial in noninfectious uveitis	1Q 2024
Batoclimab	Immunovant	Initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	1H 2024
Namilumab	Kinevant	Topline data from Phase 2 trial in sarcoidosis	2H 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. RVT-3101 is subject to a definitive agreement to sell Telavant to Roche. For more information on the Roche Transaction, please refer to Note 15 to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Recent Developments

- **Telavant:** In October 2023, Roivant entered into a definitive agreement with Roche for the sale of Telavant. Roche will gain the rights to develop, manufacture and commercialize RVT-3101 in the US and Japan for the treatment of inflammatory bowel disease and potentially other diseases. Under the terms of the agreement, Roche will pay a purchase price of $7.1 billion upfront and a milestone payment of $150 million payable upon the initiation of a Phase 3 trial in ulcerative colitis. Roivant owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%, in each case on an as-converted basis. Roivant's net proceeds from the transaction are expected to be approximately $5.2 billion plus $110 million from the milestone payment. Regulatory filings in connection with the transaction have been submitted and the closing of the transaction remains on track for the fourth quarter of 2023 or the first quarter of 2024.

- **Immunovant:** In September 2023, Immunovant announced initial data from the Phase 1 clinical trial evaluating the safety, tolerability, and pharmacodynamic profiles of IMVT-1402 in healthy adults showed that subcutaneously administered doses of IMVT-1402 produced dose-dependent reductions in Immunoglobulin G, with no statistically significant dose-related decrease in serum albumin or increase in LDL cholesterol, strengthening IMVT-1402 as a potential best-in-class neonatal fragment crystallizable receptor (FcRn) inhibitor. In October 2023, Immunovant announced the closing of an underwritten public offering and concurrent private placement offering of common stock yielding approximately $467 million in net proceeds to Immunovant, after deducting underwriting commissions and estimated offering expenses. Roivant owns approximately 55.2% of Immunovant as of November 3, 2023.

- **Dermavant:** For the second quarter ended September 30, 2023, Roivant reported VTAMA net product revenue of $18.4M, representing a 28% gross-to-net yield for the quarter. As of November 2023, over 250,000 VTAMA prescriptions have been written by approximately 12,800 unique prescribers for psoriasis, based on IQVIA data. Coverage has been expanded to 137 million US commercial lives and includes coverage by all three of the top pharmacy benefit managers.

In October 2023, Dermavant reported that in adult patients, VTAMA showed positive results from a Phase 4 open-label trial for the treatment of intertriginous plaque psoriasis - 82.8% achieved an intertriginous Physician Global Assessment (iPGA) Score of 0 (clear) or 1 (almost clear) and ≥2-grade improvement from baseline at Week 12, demonstrating compelling efficacy. Additionally, Dermavant reported in adults and children down to two years of age with atopic dermatitis, VTAMA showed rapid and significant onset of pruritus (itch) relief as early as 24 hours after initial application.

- **Roivant:** In September 2023, Roivant raised approximately $200 million in a follow-on offering. Roivant reported cash, cash equivalents and restricted cash of approximately $1.4 billion at September 30, 2023. Giving effect to Immunovant's October 2023 follow-on offering and expected cash proceeds from the pending sale of Telavant (including one-time milestone), Roivant's cash, cash equivalents and restricted cash would have been approximately $7.0 billion. The acquisition of Telavant is subject to customary closing conditions and is expected to close in the fourth quarter of 2023 or the first quarter of 2024.

Components of Results of Operations

Product revenue, net

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

License, milestone and other revenue

License, milestone and other revenue includes the recognition of 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 through preclinical studies and clinical trials, as well as acquire or discover new product candidates. We expect higher employee-related expenses, including share-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity.

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

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

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

Acquired in-process research and development expenses

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

Consideration for the purchase of IPR&D through asset acquisitions and license agreements 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. SG&A employees include those responsible for the identification and acquisition or in-license of new drug candidates as well as for managing Vant operations and facilitating the use of our platform and technologies at the Vants. SG&A expenses also consist of marketing programs, advertising, legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations. 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 loss on equity investments in publicly-traded companies, including Arbutus Biopharma Corporation ("Arbutus"), as well as our equity investment in Heracles Parent, L.L.C., the parent entity of the Datavant business ("Datavant"). We have elected the fair value option to account for these investments.

Change in fair value of debt and liability instruments

Change in fair value of debt and liability instruments primarily includes the loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including debt issued by a wholly-owned subsidiary of Dermavant Sciences Ltd. 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.

Interest income

Interest income consists of interest earned on our cash equivalents.

Interest expense

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

Income tax expense

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

Net loss attributable to noncontrolling interests

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

Results of Operations

Comparison of the three and six months ended September 30, 2023 and 2022

The following table sets forth our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Revenues:			
Product revenue, net	$ 18,424	$ 4,969	$ 13,455
License, milestone and other revenue	18,677	7,564	11,113
Revenue, net	37,101	12,533	24,568
Operating expenses:			
Cost of revenues	3,266	3,641	(375)
Research and development	131,984	131,995	(11)
Acquired in-process research and development	13,950	—	13,950
Selling, general and administrative	164,355	157,663	6,692
Total operating expenses	313,555	293,299	20,256
Loss from operations	(276,454)	(280,766)	4,312
Change in fair value of investments	45,849	54,678	(8,829)
Change in fair value of debt and liability instruments	21,533	(13,541)	35,074
Gain on deconsolidation of subsidiaries	(17,354)	(16,762)	(592)
Interest income	(14,299)	(5,670)	(8,629)
Interest expense	9,247	8,335	912
Other expense, net	5,931	5,950	(19)
Loss before income taxes	(327,361)	(313,756)	(13,605)
Income tax expense	3,757	2,165	1,592
Net loss	(331,118)	(315,921)	(15,197)
Net loss attributable to noncontrolling interests	(26,791)	(24,331)	(2,460)
Net loss attributable to Roivant Sciences Ltd.	$ (304,327)	$ (291,590)	$ (12,737)

The following table sets forth our results of operations for the six months ended September 30, 2023 and 2022:

	Six Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Revenues:			
Product revenue, net	$ 35,083	$ 5,110	$ 29,973
License, milestone and other revenue	23,642	11,742	11,900
Revenue, net	58,725	16,852	41,873
Operating expenses:			
Cost of revenues	7,480	5,367	2,113
Research and development	257,117	267,825	(10,708)
Acquired in-process research and development	26,450	—	26,450
Selling, general and administrative	320,545	306,735	13,810
Total operating expenses	611,592	579,927	31,665
Loss from operations	(552,867)	(563,075)	10,208
Change in fair value of investments	53,413	79,225	(25,812)
Change in fair value of debt and liability instruments	76,045	27,672	48,373
Gain on deconsolidation of subsidiaries	(17,354)	(16,762)	(592)
Interest income	(31,014)	(7,651)	(23,363)
Interest expense	18,159	10,947	7,212
Other expense, net	1,338	7,035	(5,697)
Loss before income taxes	(653,454)	(663,541)	10,087
Income tax expense	5,509	6,164	(655)
Net loss	(658,963)	(669,705)	10,742
Net loss attributable to noncontrolling interests	(62,820)	(46,306)	(16,514)
Net loss attributable to Roivant Sciences Ltd.	$ (596,143)	$ (623,399)	$ 27,256

Variance analysis for three and six months ended September 30, 2023 and 2022

Revenue, net

For the three months ended September 30, 2023 and 2022, our revenue consisted of the following:

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Product revenue, net	$ 18,424	$ 4,969	$ 13,455
License, milestone and other revenue	18,677	7,564	11,113
Revenue, net	$ 37,101	$ 12,533	$ 24,568

Product revenue, net increased by $13.5 million to $18.4 million for the three months ended September 30, 2023, compared to $5.0 million for the three months ended September 30, 2022. Product revenue, net consists of net product revenues from VTAMA sales, following the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022. License, milestone and other revenue increased by $11.1 million to $18.7 million for the three months ended September 30, 2023, compared to $7.6 million for the three months ended September 30, 2022. The increase was primarily driven by $15.0 million of revenue relating to milestone income at Dermavant pursuant to a collaboration and license agreement with Japan Tobacco Inc. during the three months ended September 30, 2023.

For the six months ended September 30, 2023 and 2022, our revenue consisted of the following:

	Six Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Product revenue, net	$ 35,083	$ 5,110	$ 29,973
License, milestone and other revenue	23,642	11,742	11,900
Revenue, net	$ 58,725	$ 16,852	$ 41,873

Product revenue, net increased by $30.0 million to $35.1 million for the six months ended September 30, 2023, compared to $5.1 million for the six months ended September 30, 2022. Product revenue, net consists of net product revenues from VTAMA sales, following the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022. License, milestone and other revenue increased by $11.9 million to $23.6 million for the six months ended September 30, 2023, compared to $11.7 million for the six months ended September 30, 2022. The increase was primarily driven by $15.0 million of revenue relating to milestone income at Dermavant pursuant to a collaboration and license agreement with Japan Tobacco Inc. during the six months ended September 30, 2023.

Cost of revenues

For the three months ended September 30, 2023 and 2022**,** our cost of revenues consisted of the following:

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Cost of product and other revenues	$ 867	$ 1,441	$ (574)
Amortization of intangible assets	2,399	2,200	199
Cost of revenues	$ 3,266	$ 3,641	$ (375)

Cost of revenues decreased by $0.4 million to $3.3 million for the three months ended September 30, 2023 compared to $3.6 million for the three months ended September 30, 2022. During each of the three months ended September 30, 2023 and 2022, cost of revenues included $0.5 million of costs relating to VTAMA sales as well as amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022.

For the six months ended September 30, 2023 and 2022, our cost of revenues consisted of the following:

	Six Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Cost of product and other revenues	$ 2,711	$ 2,425	$ 286
Amortization of intangible assets	4,769	2,942	1,827
Cost of revenues	$ 7,480	$ 5,367	$ 2,113

Cost of revenues increased by $2.1 million to $7.5 million for the three months ended September 30, 2023 compared to $5.4 million for the six months ended September 30, 2022. During the six months ended September 30, 2023 and 2022, cost of revenues included $1.3 million and $0.7 million, respectively, of costs relating to VTAMA sales as well as amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022.

Research and development expenses

For the three months ended September 30, 2023 and 2022**,** our research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2023	**2022**	**Change**
		(in thousands)	
Program-specific costs:			
Anti-FcRn franchise[(1)]	$ 25,919	$ 19,464	$ 6,455
RVT-3101	18,553	—	18,553
Tapinarof	9,351	12,543	(3,192)
Brepocitinib	8,755	8,592	163
RVT-2001	3,739	4,646	(907)
Namilumab	3,331	5,091	(1,760)
Other development and discovery programs	12,867	31,021	(18,154)
Total program-specific costs	82,515	81,357	1,158
Unallocated internal costs:			
Share-based compensation	8,877	7,417	1,460
Personnel-related expenses	29,841	35,268	(5,427)
Other expenses	10,751	7,953	2,798
Total research and development expenses	$ 131,984	$ 131,995	$ (11)

(1) Reflects program-specific costs relating to Immunovant's batoclimab program for the treatment of neurology and endocrine diseases and Immunovant's IMVT-1402 program. Certain prior period amounts have been reclassified to conform to current period presentation.

Research and development expenses were $132.0 million for each of the three months ended September 30, 2023 and 2022. Changes in the components of research and development expenses included a decrease in personnel-related expenses of $5.4 million and increases in share-based compensation expense of $1.5 million and program-specific costs of $1.2 million.

Within program-specific costs, the primary drivers of change during the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 were an additional expense of $18.6 million related to RVT-3101, which was acquired in November 2022, and a decrease in expenses related to other development and discovery programs of $18.2 million, which in part resulted from the deconsolidation of Proteovant Sciences, Inc. ("Proteovant") in August 2023 along with the reprioritization of certain programs and drug discovery efforts.

For the six months ended September 30, 2023 and 2022**,** our research and development expenses consisted of the following:

	Six Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Program-specific costs:			
Anti-FcRn franchise[(1)]	$ 54,957	$ 30,136	$ 24,821
RVT-3101	29,478	—	29,478
Tapinarof	18,894	22,983	(4,089)
Brepocitinib	16,518	20,894	(4,376)
RVT-2001	7,561	6,769	792
Namilumab	6,633	6,109	524
Other development and discovery programs	21,193	74,969	(53,776)
Total program-specific costs	155,234	161,860	(6,626)
Unallocated internal costs:			
Share-based compensation	16,830	19,660	(2,830)
Personnel-related expenses	63,443	69,715	(6,272)
Other expenses	21,610	16,590	5,020
Total research and development expenses	$ 257,117	$ 267,825	$ (10,708)

(1) Reflects program-specific costs relating to Immunovant's batoclimab program for the treatment of neurology and endocrine diseases and Immunovant's IMVT-1402 program. Certain prior period amounts have been reclassified to conform to current period presentation.

Research and development expenses decreased by $10.7 million to $257.1 million for the six months ended September 30, 2023 compared to $267.8 million for the six months ended September 30, 2022, primarily due to decreases in program-specific costs of $6.6 million, personnel-related expenses of $6.3 million, and share-based compensation of $2.8 million, partially offset by an increase of other expenses of $5.0 million.

The decrease of $6.6 million in program-specific costs was primarily driven by a decrease of $53.8 million in other development and discovery program expense, which in part resulted from the deconsolidation of Proteovant in August 2023 along with the reprioritization of certain programs and drug discovery efforts. This decrease was partially offset by increases of $29.5 million relating to RVT-3101, which was acquired in November 2022, and $24.8 million relating to the anti-FcRn franchise.

Acquired in-process research and development expenses

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Acquired in-process research and development	$ 13,950	$ —	$ 13,950	$ 26,450	$ —	$ 26,450

Acquired in-process research and development expenses were $14.0 million for the three months ended September 30, 2023 due to $14.0 million of consideration for the purchase of IPR&D relating to an asset acquisition completed by a newly-formed subsidiary.

Acquired in-process research and development expenses were $26.5 million for the six months ended September 30, 2023 due to $14.0 million of consideration for the purchase of IPR&D relating to an asset acquisition completed by a newly-formed subsidiary and $12.5 million relating to the achievement of development and regulatory milestones for batoclimab.

Selling, general and administrative expenses

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Selling, general and administrative	$ 164,355	$ 157,663	$ 6,692	$ 320,545	$ 306,735	$ 13,810

Selling, general and administrative expenses increased by $6.7 million to $164.4 million for the three months ended September 30, 2023 compared to $157.7 million for the three months ended September 30, 2022, primarily due to an increase in selling, general and administrative expenses of $21.8 million at Dermavant as a result of the progression of the commercial launch of VTAMA, partially offset by a decrease of $14.2 million of share-based compensation expense.

Selling, general and administrative expenses increased by $13.8 million to $320.5 million for the six months ended September 30, 2023 compared to $306.7 million for the six months ended September 30, 2022, primarily due to an increase in selling, general and administrative expenses of $48.9 million at Dermavant as a result of the progression of the commercial launch of VTAMA, partially offset by a decrease of $33.5 million of share-based compensation expense.

Change in fair value of investments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Change in fair value of investments	$ 45,849	$ 54,678	$ (8,829)	$ 53,413	$ 79,225	$ (25,812)

Change in fair value of investments were unrealized losses of $45.8 million and $54.7 million for the three months ended September 30, 2023 and 2022, respectively. The change of $8.8 million was primarily driven by changes in the public share prices of our equity investments, including Arbutus, as well as the change in fair value of our investment in Datavant.

Change in fair value of investments were unrealized losses of $53.4 million and $79.2 million for the six months ended September 30, 2023 and 2022, respectively. The change of $25.8 million was primarily driven by changes in the public share prices of our equity investments, including Arbutus, as well as the change in fair value of our investment in Datavant.

Change in fair value of debt and liability instruments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Change in fair value of debt and liability instruments	$ 21,533	$ (13,541)	$ 35,074	$ 76,045	$ 27,672	$ 48,373

Change in fair value of debt and liability instruments was a loss of $21.5 million and gain of $13.5 million for the three months ended September 30, 2023 and 2022, respectively. Change in fair value of debt and liability instruments for the three months ended September 30, 2023 primarily consisted of a loss of $11.7 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination and a loss of $9.7 million relating to the NovaQuest Facility, which was largely due to the passage of time. Change in fair value of debt and liability instruments for the three months ended September 30, 2022 primarily consisted of a gain of $4.8 million relating to the NovaQuest facility, which was largely due to increased interest rates, and a gain of $8.8 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 were losses of $76.0 million and $27.7 million for the six months ended September 30, 2023 and 2022, respectively. Change in fair value of debt and liability instruments for the six months ended September 30, 2023 primarily consisted of a loss of $51.7 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination and a loss of $24.1 million relating to the NovaQuest Facility, which was largely due to the passage of time. The change in fair value of debt and liability instruments for the six months ended September 30, 2022 primarily consisted of a loss of $53.1 million relating to the NovaQuest facility, which was primarily due to the impact of VTAMA approval in psoriasis, partially offset by a gain of $19.5 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination.

Gain on deconsolidation of subsidiaries

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Gain on deconsolidation of subsidiaries	$ (17,354)	$ (16,762)	$ (592)	$ (17,354)	$ (16,762)	$ (592)

Gain on deconsolidation of subsidiaries was $17.4 million for the three and six months ended September 30, 2023 and resulted from the deconsolidation of VantAI Holdings, Inc. ("VantAI") in July 2023 and Proteovant in August 2023.

Gain on deconsolidation of subsidiaries was $16.8 million for the three and six months ended September 30, 2022 and resulted from the deconsolidation of Cytovant Sciences HK Limited in July 2022.

Interest income

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Interest income	$ (14,299)	$ (5,670)	$ (8,629)	$ (31,014)	$ (7,651)	$ (23,363)

Interest income increased by $8.6 million to $14.3 million for the three months ended September 30, 2023, compared to $5.7 million for the three months ended September 30, 2022. The increase is primarily the result of higher interest rates on our invested cash.

Interest income increased by $23.4 million to $31.0 million for the six months ended September 30, 2023, compared to $7.7 million for the six months ended September 30, 2022. The increase is primarily the result of higher interest rates on our invested cash.

Interest expense

	Three Months Ended September 30,			Six Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
		(in thousands)			*(in thousands)*	
Interest expense	$ 9,247	$ 8,335	$ 912	$ 18,159	$ 10,947	$ 7,212

Interest expense increased by $0.9 million to $9.2 million for the three months ended September 30, 2023, compared to $8.3 million for the three months ended September 30, 2022.

Interest expense increased by $7.2 million to $18.2 million for the six months ended September 30, 2023, compared to $10.9 million for the six months ended September 30, 2022. The increase primarily resulted from Dermavant's revenue interest purchase and sale agreement (the "RIPSA"), pursuant to which funding of $160.0 million was received in June 2022 following the approval of VTAMA by the FDA in May 2022.

Liquidity and Capital Resources

For the six months ended September 30, 2023 and 2022, we incurred net losses of approximately $659.0 million and $669.7 million, respectively. As of September 30, 2023, we had cash and cash equivalents of approximately $1.4 billion and our accumulated deficit was approximately $4.4 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 operations to date have been financed primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements.

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

In October 2023, Immunovant completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by us on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of $38.00 per share. Concurrent with the public offering, we purchased 4,473,684 shares of Immunovant's common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of $38.00 per share. The net proceeds to Immunovant were approximately $466.6 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses.

On October 22, 2023, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with our subsidiary Telavant Holdings, Inc. ("Telavant"), Pfizer Inc. ("Pfizer") and Roche Holdings, Inc. ("Roche"), pursuant to which Roche agreed to acquire all of the issued and outstanding shares of capital stock of Telavant on the terms and subject to the conditions set forth in the Purchase Agreement (the "Roche Transaction"). Telavant holds the rights to RVT-3101, an anti-TL1A antibody in development for ulcerative colitis ("UC") and Crohn's disease. We own 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%, in each case on an as-converted basis.

The total consideration to be paid by Roche is comprised of (i) $7.1 billion in cash at the closing of the Roche Transaction, subject to certain customary adjustments as set forth in the Purchase Agreement, and (ii) a one-time milestone payment of $150 million in cash payable upon the initiation of a Phase 3 trial in UC, as described in more detail in the Purchase Agreement, in each case to be paid to all of Telavant's equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction. We expect to receive cash proceeds of approximately $5.2 billion upon closing of the Roche Transaction and are eligible to receive approximately $110 million for our portion of a one-time milestone payment upon Phase 3 initiation in UC.

The Roche Transaction is expected to close in the fourth quarter of calendar year 2023 or the first quarter of calendar year 2024. The closing of the Roche Transaction is subject to the satisfaction or waiver of certain customary closing conditions, including certain regulatory approvals. The Purchase Agreement contains customary representations, warranties and covenants related to the Roche Transaction. The Purchase Agreement also includes customary termination provisions and provides that, if the Roche Transaction has not been consummated by July 23, 2024, the parties may terminate the Purchase Agreement and abandon the Roche Transaction.

Our short-term and long-term liquidity requirements as of September 30, 2023 included:

- contractual payments related to our long-term debt (see Note 7, "Long-Term Debt" of our condensed consolidated financial statements);
- obligations under our leases;
- certain commitments to Palantir Technologies Inc. ("Palantir") totaling $19.1 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 $18.7 million; and
- certain commitments to GSK pursuant to a commercial supply agreement entered between Dermavant and GSK. In conjunction with Dermavant's entry into the GSK Agreement in 2018, Dermavant entered into a clinical supply agreement pursuant to which GSK would provide a supply of tapinarof and clinical product at an agreed upon price during our clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed upon minimum quantities and 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 agreed to provide a supply of tapinarof to Dermavant at an agreed upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. The minimum purchase commitment related to these agreements is estimated to be approximately $42.6 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 leases during the three months ended September 30, 2023 outside the ordinary course of business. For further information regarding our lease commitments, refer to Note 15, "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.

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 six months ended September 30, 2023 and 2022:

	Six Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (446,359)	$ (441,712)
Net cash used in investing activities	$ (36,346)	$ (154,311)
Net cash provided by financing activities	$ 215,349	$ 134,635

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 six months ended September 30, 2023, cash used in operating activities increased by $4.6 million to $446.4 million compared to the six months ended September 30, 2022.

Investing Activities

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

For the six months ended September 30, 2023 and 2022, cash flow from investing activities changed by $118.0 million to net cash used in investing activities of $36.3 million from net cash used in investing activities of $154.3 million for the six months ended September 30, 2022. This change in cash flow is primarily due to milestone payments relating to VTAMA made during the six months ended September 30, 2022, partially offset by activity relating to the deconsolidation of Proteovant and VantAI during the six months ended September 30, 2023.

Financing Activities

For the six months ended September 30, 2023, cash provided by financing activities increased by $80.7 million to $215.3 million compared to the six months ended September 30, 2022. During the six months ended September 30, 2023, net proceeds were primarily generated by the issuance of our common shares pursuant to purchase and sale agreements entered with certain institutional investors. During the six months ended September 30, 2022, proceeds were generated by funding pursuant to the terms of the RIPSA following the approval of VTAMA by the FDA in May 2022.

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.

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, 2023 in our Form 10-K.

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 September 30, 2023, 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 September 30, 2023 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 September 30, 2023 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 commercial-stage biopharmaceutical and healthcare technology company with a limited operating history upon which you can evaluate our business and prospects. We were formed in April 2014, and our operations to date have primarily been limited to acquiring or in-licensing product candidates, pursuing the clinical development and commercialization of those product candidates, efforts to discover new product candidates, financing activities and the creation or acquisition of healthcare technology companies and products, as well as the oversight and management of our subsidiaries developing and commercializing medicines, which we refer to as "Vants."

Last year, following the approval by the U.S. Food and Drug Administration (the "FDA") in May 2022 of VTAMA® (tapinarof) for the treatment of adults with plaque psoriasis, we commenced our transition from a clinical-stage to a company with commercial-stage assets. VTAMA is not currently approved in any other jurisdictions and we do not have any other product candidates that have received regulatory approvals in the U.S. or in any other jurisdiction.

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

- successfully continue to commercialize VTAMA;
- 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 discovery efforts and advance those product candidates into preclinical studies and clinical trials;
- successfully grow our healthcare technology Vants and market the products and services offered by those Vants;
- 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 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 when and if our products and product candidates will achieve various milestones in their clinical development, including marketing approval from the FDA or other regulatory authorities, the timing or amount of increased expenses related to these activities or when we will be able to generate meaningful revenues or achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities to perform studies or clinical trials in addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development in the U.S. or another jurisdiction, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our product candidates that we may identify. We anticipate incurring significant costs associated with commercializing VTAMA and any future product candidates, if approved, and advancing our ongoing clinical trials and discovery efforts until our revenue from product sales of VTAMA and any other approved products exceeds such expenses, which may never occur.

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 significant product revenues from the commercial sale of our biopharmaceutical products. We cannot estimate with precision the extent of our future losses. Since inception, we have incurred significant losses and negative cash flows from operations. As of September 30, 2023, we had cash and cash equivalents of approximately $1.4 billion and an accumulated deficit of approximately $4.4 billion.

We may never be able to develop new marketable drugs, 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 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 our 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 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 and retain access to physicians or persuade adequate numbers of physicians to prescribe VTAMA and any future products;
- the inability to manufacture and to price VTAMA and any future products at a price point sufficient to ensure an adequate and attractive level of profitability;
- the extent to which coverage and adequate reimbursement for VTAMA and any future products will be available from government health administration authorities, private health insurers and other organizations;

- the risks associated with potential co-promotion or partnership agreements, including the failure to realize the expected benefits of such arrangements; and

- other unforeseen costs, expenses and risks associated with the commercialization of biopharmaceutical products, including compliance costs.

In addition, in connection with our continued commercialization of VTAMA, we expect to continue to increase the amount of cash we spend in order to expand our commercial infrastructure. 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 those outlined herein. Further, given our limited experience of commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. As we continue to develop and seek regulatory approval of additional products and product candidates, as well as additional indications for VTAMA, and to pursue regulatory approvals for VTAMA and other products and product candidates outside the U.S., it could be difficult for us to obtain and devote the resources necessary to successfully 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.

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.

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

We currently have one product approved by the FDA – VTAMA, which was approved for the treatment of plaque psoriasis in adults in the U.S. The success of our business, including our ability to finance our company and generate any revenue in the future, will depend to a significant extent on the successful commercialization of VTAMA and the successful development, regulatory approval, and commercialization of other product candidates. The commercial success of VTAMA and the clinical and commercial success of other product candidates will depend on a number of factors, including the following:

- our ability to successfully implement and execute on a marketing strategy for VTAMA and to commercialize any of our product candidates in the United States and internationally, if approved, whether alone or in collaboration with others;

- acceptance by physicians, payers, and patients of the benefits, safety, and efficacy of VTAMA or any product candidates, if approved, including relative to alternative and competing treatments;

- timely completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;

- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

- acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

- the prevalence, duration, and severity of potential side effects or other safety issues experienced with VTAMA or our product candidates;

- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

- achieving, maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to VTAMA or any of our product candidates;

- the willingness of physicians and patients to utilize or adopt VTAMA and our product candidates, if approved;

- the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of VTAMA or any of our product candidates to remain in good standing with relevant regulatory authorities and to develop, validate, and maintain commercially viable manufacturing processes that are compliant with Current Good Manufacturing Practice ("cGMP");

- the availability of coverage and adequate reimbursement from private third-party payers and governmental healthcare programs, such as Medicare and Medicaid;

- patient demand for any approved products;

- our ability to establish and enforce intellectual property rights in and to any current and future products and product candidates;

- our ability to avoid third-party patent interference, intellectual property challenges, or intellectual property infringement claims; and

- the ability to raise any additional required capital on acceptable terms, or at all.

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

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

The success of our business depends in large 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. Any such failure to in-license or acquire new product candidates from third parties would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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 do not wholly-own many of our Vants, and certain of our Vants have issued debt or equity securities senior to our ownership interests, which dilutes our economic interest in the Vants. Future capital needs at individual Vants may also be financed through senior debt or equity securities, or common equity, all of which may further dilute our economic interest in a Vant.

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

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

Our asset in-licensing transactions typically involve zero or low upfront payments combined with milestone and royalty payments. These arrangements generally involve a payment or payments upon the achievement of certain development or regulatory milestones, including regulatory approval, and then royalty payments upon the achievement of specified levels of sales, which can extend for up to the life of a product. Some of these payments may become due before a product is generating 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 and our ability to in-license future product candidates could be impaired.

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

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

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

From time to time, we may consider strategic transactions, including acquisitions or divestitures of companies, asset purchases or sales and out-licensing or in-licensing of intellectual property, products or technologies. For example, on October 23, 2023, we announced entry into a definitive agreement with Roche to sell Telavant, which is owned by us and Pfizer, to Roche for aggregate upfront consideration of $7.1 billion and a near-term, one-time milestone payment of $150 million (the “Roche Transaction”). Additional potential transactions that we may consider in the future include a variety of business arrangements, including spinoffs, strategic partnerships, joint ventures, collaborations, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our or our Vants’ equity securities, including our Common Shares, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, and could expose us to the risk of litigation, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions, including the Roche Transaction, may never be successful and may require significant time and attention of our management, as well as significant costs, whether or not successfully consummated. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. For any alliances or joint ventures that we enter into in the biopharmaceutical industry, we may encounter numerous difficulties in discovering, developing, manufacturing and marketing any new products or product candidates related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. Divestiture transactions such as the Roche Transaction, if they were to occur, may adversely impact the price of our common shares, to the extent investors believe the value of the consideration received in the transaction is not equivalent to the value of the asset or program divested. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, including the Roche Transaction, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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 pursue these activities. We are also responsible for payments to third parties under our license and acquisition agreements, including milestone and royalty payments. Because of the inherent uncertainties in these activities – including the outcome of preclinical and clinical trials and the regulatory approval process – we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our current and future products and product candidates.

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

- the time and costs necessary to complete our ongoing, planned and future clinical trials;
- 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 pursuing and defending potential intellectual property disputes, including patent infringement actions with third parties relating to our current or future products or product candidates; and
- our ability to hire, attract and retain qualified personnel.

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, rising interest rates and increasing market and banking sector instability and volatility, all of which have been observed in recent periods, may further adversely impact our ability to obtain financing on acceptable terms or at all.

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.

Our business, operations and clinical development timelines are subject to risks arising from the COVID-19 pandemic and other epidemic diseases.

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and has affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken, and may continue to take, actions in an effort to slow the spread of COVID-19 and variants of the virus. The continued spread of COVID-19 and the measures taken by governmental authorities, and any future epidemic or pandemic disease outbreaks, may cause disruptions that could severely impact our business, preclinical studies, clinical trials and financial condition, including by:

- disrupting the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials;
- delaying, limiting or preventing our employees and CROs from continuing research and development activities;
- impeding our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- impeding testing, monitoring, study procedures (such as endoscopies that are deemed non-essential), data collection and analysis and other related activities that may impact the integrity of subject data and clinical study endpoints; and
- affecting the business of the FDA, European Medicines Agency (“EMA”) or other regulatory authorities, which could result in delays in meetings related to ongoing or planned clinical trials.

The extent to which the COVID-19 pandemic or any future pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus, the identification of new variants, the rate of vaccine administration and the actions taken to contain its impact. The FDA issued a number of guidance documents describing its expectations for how drug manufacturers should comply with various FDA requirements during the COVID-19 pandemic and has otherwise exercised enforcement discretion as to certain requirements due to the related public health emergency. 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”) ended on May 11, 2023, 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 in the near term. In anticipation of these events, the FDA published a notice in the Federal Register indicating which guidance documents will immediately cease upon termination of the emergency declaration under the PHSA as well as those that will be revised or continue for a limited or indefinite time. As a result, we may assume a greater compliance burden in connection with our ongoing clinical trials.

The COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. To the extent the COVID-19 pandemic or any future pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

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

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

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 ongoing effects of the COVID-19 pandemic or future pandemics may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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.

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, including those related to the ongoing COVID-19 pandemic or future pandemics, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our products and product candidates, including 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 preclinical studies and clinical trials may not support our proposed claims for our products or product candidates, or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior preclinical studies and earlier clinical trials. For example, we cannot assure you that the efficacy and safety results from our TUSCANY-2 trial of RVT-3101 in ulcerative colitis or the reductions in IgG antibodies and favorable analyte profile observed in our Phase 1 trial of IMVT-1402 and will be observed in future clinical trials, including pivotal trials necessary for regulatory approvals. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unobserved adverse events.

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

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

From time to time, and in some countries, in line with the applicable requirements set out in legislation and guidance, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data. For example, earlier this year we disclosed interim and chronic period data from the TUSCANY-2 trial of RVT-3101 in ulcerative colitis, top-line data from our pivotal atopic dermatitis Phase 3 ADORING 1 and ADORING 2 trials of VTAMA and initial human data from our Phase 1 trial of IMVT-1402. These results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously reported. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares.

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

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

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

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

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

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

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

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

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

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

Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our products or product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our products for commercialization and products or product candidates for our preclinical studies, clinical trials and research and development activities. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, or of equipment and devices as necessary, for either commercialization or an ongoing clinical trial, due to the need to replace a third-party manufacturer or otherwise, could considerably delay marketing efforts for the product in question or the completion of clinical trials, product testing and potential regulatory approval of the product candidate in question. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our products or product candidates, the commercial launch of our products or product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products or product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our products or product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involve committing substantial financial resources to current or future products or product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals were recently enacted or are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the 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, for the treatment plaque psoriasis in adults, it is possible that VTAMA will not obtain regulatory approval in the U.S. for other indications or in other jurisdictions, and that other current and future product candidates will not be successful in obtaining regulatory approval in the U.S. and other jurisdictions. In addition, we cannot be certain that any products or product candidates that receive regulatory approval will be successfully commercialized.

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

- we may not be able to demonstrate that a product candidate is safe and effective as a treatment for the targeted indications, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure and potent for use in its targeted indication, to the satisfaction of the FDA or other relevant regulatory authorities;

- the FDA or other relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase costs and prolong development timelines;

- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;

- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of clinical trials, including the design of proposed preclinical and early clinical trials of any future product candidates;

- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact the clinical trials and ability to obtain marketing approvals;

- the FDA or other relevant regulatory authorities may not find the data from nonclinical, preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks;

- the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, preclinical studies or clinical trials or may require additional studies;

- the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites, including in situations where the authorities deem that the data was not generated in compliance with GCP, ethical standards or applicable data protection laws;

- if an NDA, BLA or a similar application is 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 labelling 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. Indeed, the FDA issued Draft Guidance for Industry, Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases (January 2023), to assist sponsors in identifying the optimal dosages for these products during clinical development and prior to submitting an application for approval for a new indication and usage.

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, in early 2021, our subsidiary Immunovant voluntarily paused dosing in early phase clinical studies for batoclimab to evaluate treatment-induced elevations in total cholesterol and LDL levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory agencies, Immunovant is continuing its clinical development of batoclimab. While Immunovant does not expect that increases in LDL over a short-term treatment duration would pose a safety concern for patients, the risk-benefit profile of long-term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. These occurrences have harmed, and any reoccurrence may continue to harm our business, financial condition and prospects.

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

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

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

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

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable non-U.S. regulatory authorities, that such product candidate is safe and effective and, as applicable, pure and potent for its intended use. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval of a product candidate by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the 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, labelling, packaging, distribution, adverse event reporting, storage, recordkeeping, traceability, conduct of potential post-marketing studies and post-marketing submission requirements, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP or equivalent requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, prior notification/review and/or approval of advertising and promotional materials by the competent authorities, record-keeping and GCP requirements for any clinical trials that we conduct post-approval. Even when marketing approval of a product or product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. When a product or product candidate receives marketing approval, the accompanying label may limit the approved use of the drug or the FDA or other regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning, be included in the product labelling or accompanying documentation, which could limit sales of the product.

The FDA and other relevant regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs, result in regulatory enforcement, or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labelling and that promotional and advertising materials and communications are truthful and non-misleading. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications and if we do not market our products or product candidates for their approved indications or in a manner which regulators believe to be truthful and non-misleading, we may be subject to enforcement action. Moreover, in the EU and the UK we will be prohibited from promoting prescription-only medicinal products to individuals who are not healthcare professionals. Violations of the FDCA in the 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 labelling or marketing of such products or product candidates, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the 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. For example, in July 2021, Immunovant was granted orphan drug designation in the U.S. by the FDA for batoclimab for the treatment of MG and, in August 2022, it received orphan drug designation from the European Commission for batoclimab for the treatment of MG. Immunovant plans to seek orphan drug designation from the FDA for batoclimab and/or IMVT-1402 where there is a medically plausible basis for batoclimab and/or IMVT-1402's use. Immunovant may also seek orphan drug designation for batoclimab and/or IMVT-1402 for the treatment of other indications in the E.U. We may also do so for other of our products and product candidates in the future where there is a basis for doing so.

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

Recently, there has been heightened scrutiny of the accelerated approval pathway, with some stakeholders advocating for reform. The HHS Office of Inspector General has initiated, and partly completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Consolidated Appropriations Act, 2023, revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things, requires the FDA to specify the conditions for required post-marketing trials, permits the FDA to require such trials to be underway prior to, or within a specific period after, approval, requires sponsors to provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed, makes the failure to conduct required post-marketing trials with due diligence and the failure to submit the required reports prohibited acts, and details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis. We understand that FDA approval letters to products granted accelerated approval subsequent to passage of this legislation are including language that informs the sponsor that they are required to submit status reports of the progress of each requirement no later than 180 days post-approval and every 180 days thereafter. 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 market exclusivity scheme exists in the EEA. The European Commission, on the basis of a scientific opinion by the EMA's Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, Orphan Drug Designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to certain benefits, such as scientific assistance (protocol assistance), financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission, EMA and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the "normal" data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company's preclinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic or biosimilar drug can be marketed for ten years from the first approval of the innovator drug in the EEA; the innovator drug may qualify for an extra year's protection. This additional one year of marketing exclusivity may be obtained where the innovator company is granted, during the first eight years of the ten years market exclusivity, a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic or biosimilar company can only market their product after 11 years from the first grant of the innovator company's marketing authorization for the product in the EEA.

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

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

On April 26, 2023, as part of the EU Pharmaceutical Strategy, the European Commission published a proposal for a comprehensive revision of the EU pharmaceutical legislation (which will not apply in the UK). If adopted by the European Parliament and the Council, the new legislation is likely to significantly change the regulatory regime applicable to both the "normal" data and market exclusivity and the orphan exclusivities and reduce/modulate the exclusivities and rewards that could be granted to medicinal products. In addition, the proposal envisages changes to the concept of unmet medical need and considers introducing novel rewards for orphan medicinal products addressing a high unmet medical need. The adoption of the new legislation is not expected before 2024 and it will start to apply 18 months after the entry in force.

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

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

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

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

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

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

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

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

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

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 further building out our commercial sales organization for the sales, marketing and distribution of VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U.S. 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 $13,508 to $27,018 for each false claim or statement for penalties assessed after January 30, 2023, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 ("HIPAA")), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses and most healthcare providers (collectively, "covered entities"), and such covered entities' "business associates," defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of the covered entity;

- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personally identifiable data, including personal health information;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

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

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

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

The 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 labelling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the 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 replaced as a part of the Part D benefit redesign enacted under the Inflation Reduction Act of 2022 ("IRA").

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 2032 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. There was a 1% reduction through the end of June 2022, after which the cuts returned to 2%. Absent further Congressional action, there is a possibility that an up to 4% Medicare sequester could be triggered in January 2025, pursuant to the Statutory Pay-As-You-Go Act of 2010 ("PAYGO"). Under PAYGO, if the five- or ten-year PAYGO scorecard shows a net cost at the end of a Congressional session, then the Office of Management and Budget is required to issue a sequestration order. The American Rescue Plan Act of 2021 was expected to trigger a PAYGO sequestration order at the end of the 2021 Congressional session. However, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024.

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 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. There are several ongoing legal challenges to the IRA's drug price negotiation program, and we cannot predict the outcome of these cases or the impact they could have on implementation of the law. 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. In response, the CMS innovation center released a report in February 2023, identifying three selected models: Medicare High-Value Drug Model, the Cell & Gene Therapy Access Model, and the Accelerating Clinical Evidence Model. We cannot predict how these new provisions would be implemented or their impact on Roivant. Moreover, several states have passed, or are considering, legislation related to drug price transparency or controlling drug costs. For example, some state legislatures have established Prescription Drug Affordability Boards ("PDABs"), which under certain circumstances may conduct affordability reviews and establish upper payment limits for drugs purchased in the state. On August 4, 2023, the Colorado PDAB commenced an affordability review of five prescription drugs, including three products that are indicated to treat plaque psoriasis (ENBREL®, COSENTYX®, STELARA®). We cannot predict the outcome of this affordability review, whether the Colorado PDAB will establish upper payment limits for one or more of these drugs, or the impact of any such upper payment limit on utilization of VTAMA. We may continue to see additional state action related to prescription drug pricing.

Additionally, U.S. regulators continue to pursue policies designed to lower drug costs for federal programs and patients. In May 2019, the CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. This rulemaking also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. However, Congress has adopted various delays on the implementation or enforcement of the rule, including a postponement until January 2032 under the IRA. On December 31, 2020, CMS enacted a final rule expanding the scope of drug products that may be considered "line extensions" subject to inflationary rebates under the Medicaid Drug Rebate Program. On May 23, 2023, CMS issued a Medicaid Drug Rebate Program proposed rule, which if finalized, would among other things, require drug manufacturers to aggregate certain price concessions when calculating Best Price, establish a price verification survey, and amend the definitions of a "covered outpatient drug" and a "manufacturer." These changes, if finalized, could deepen rebates owed on Medicaid utilization, expand the scope of products subject to Medicaid rebates, and subject manufacturer drug pricing practices to further scrutiny.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the national and state levels in jurisdictions around the world directed at containing or lowering the cost of healthcare, including prescription drugs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, 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. For example, while we have previously disclosed successes in achieving payor coverage for VTAMA, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Discussions with payors, including PBMs, related to VTAMA are ongoing and whether such payors will provide coverage for VTAMA, and if so to what extent, is uncertain at this time. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product or, if approved, product candidates, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product or product candidate. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products or, if approved, product candidates, to the extent that patients who are prescribed our products or, if approved, product candidates, are not separately reimbursed for the cost of the product.

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

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the 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 the UK there is also a budget cap on branded health service medicines, and there are currently ongoing consultations in the UK that may increase the level of rebate payment that a company is required to make to the National Health Service to take account of any spend on branded products that is above the agreed cap. 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. The court dismissed the case in February 2023. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC"), for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. 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, including our Principal Executive Officer, Matthew Gline, as well as other senior executives at Roivant and the Vants. We rely greatly on the investment experience and medical and scientific expertise of our senior leadership team to identify product candidates and guide future investments and opportunities, as well as the drug development expertise of our and the Vants' senior leadership to guide the preclinical and clinical development of our product candidates. Our success will depend on our ability to retain our current management team. In addition, while we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties related to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. Competition for senior leadership in the healthcare investment industry is intense, and we cannot guarantee that we will be able to retain our key personnel or that of our Vants.

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

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

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

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

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

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

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

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our products or, if approved, product candidates, in various countries;
- difficulties in managing operations in different jurisdictions;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to currency exchange rate fluctuations;
- varying protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the 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 and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by global or regional economic, political and health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), trade disputes between nations and the current and future conditions in the global financial markets. For example, if sustained high rates of inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease (for example, COVID-19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and/or medications, which could have a negative impact on our commercial sales. The COVID-19 outbreak, including developments involving subsequent COVID-19 variants, significantly affected the financial markets of many countries and resulted and may in the future result in a variety of federal, state and local orders, guidance and restrictions. We cannot, at this time, predict the continued impact that the COVID-19 pandemic will have on our ongoing and planned clinical trials and other business operations, including our commercialization activities. A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

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

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

- ZORYVE (roflumilast), a topical PDE4 inhibitor, a potential competitor to VTAMA;
- OPZELURA (ruxolitinib), a topical Janus kinase inhibitor, a potential competitor to VTAMA;
- MK-7240 (previously PRA023), a TL1A antibody, a potential competitor to RVT 3101;
- VYVGART (efgartigimod alfa-fcab) and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), neonatal Fc receptor blockers, potential competitors to batoclimab and IMVT-1402;
- Nipocalimab and RYSTIGGO (rozanolixizumab-noli), 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We cannot anticipate all possible types of security threats and we cannot guarantee that our data protection efforts and our investments in information technology will prevent significant breakdowns, data leakages, security breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If a significant cybersecurity compromise were to occur, it could result in a material disruption of our commercialization efforts, drug development programs and other business operations. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we rely on third parties to supply components for and to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or in an 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 requirements relating to the privacy, security, transmission and disposal of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. 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 (including clinical trial investigators) that are subject those regulations, and we have to expend resources to understand their obligations, adjust contractual terms in light of those obligations, or otherwise modify our business practices. Congress is actively considering adopting legislation to regulate the collection, use, and disclosure of personal health information more broadly than the HIPAA privacy and security regulations. Such legislation might require us to make substantial expenditures and would likely create additional liability risks.

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

In addition, 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 complicates compliance efforts. For example, the California Confidentiality of Medical Information Act (the "CMIA"), a statute that expressly applies to pharmaceutical companies (as well as companies that provide certain technologies for processing personal health information), imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA, with limited exceptions, requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information and requires pharmaceutical companies to maintain reasonable security measures to protect such information. The CMIA authorizes administrative fines and civil penalties of up to $25,000 for willful violations and up to $250,000 if the violation is for purposes of financial gain, as well as criminal fines. In addition, another more broadly applicable California law, the California Consumer Privacy Act of 2018 (the "CCPA"), which was 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 the legislatures of other states, including Colorado, Connecticut, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah, and Virginia, all of which have passed CCPA/CPRA-like legislation to provide their respective residents with similar rights. Recently, both Nevada and Washington State enacted laws to protect the privacy of personal health information specifically, both of which generally require consent for the collection, use, or sharing of any such information. Violations of the Washington State law can result in civil penalties of up to $7,500 per violation, up to $25,000 in treble damages at the sole discretion of the court, and injunctive relief. Consumers also may bring their own actions to recover (i) actual damages, (ii) treble damages; and (iii) attorney's fees. Violations of the Nevada law can result in up to $10,000 civil penalties per violation and injunctive relief.

New legislation anticipated to be enacted in various other states will continue to shape the data privacy environment nationally. The effects on our business of this growing body of privacy and data protection laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Outside of the 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 – the EU-U.S. Data Privacy Framework ("DPF") was since developed. In July 2023, the U.S. and EU implemented the DPF. Companies can now use this new mechanism to transfer personal data from the EU to the U.S. and potentially from Switzerland to the U.S., subject to national implementation in Switzerland. The UK Extension to the EU-U.S. Data Privacy Framework ("Data Bridge") entered into force on October 12, allowing certifying entities to transfer personal data from the UK to the U.S. At the moment, it is unclear whether the anticipated legal challenges against the DPF, which may 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 and the DPF, any transfers by us or our vendors of personal information from Europe may not comply with European data protection laws, which may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of 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, this adequacy decisions will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or unilaterally revoked in the interim at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data.

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 FTC, EU Data Protection Authorities and other regulatory authorities in relation to privacy and cybersecurity matters can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In the 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 current practices. Significant resources are needed to understand and comply with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties, including government-imposed fines or orders requiring that we change our practices or unwind certain lines of business, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even absent any findings that we have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

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

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

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

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

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

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

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have acquired insurance coverage which extends to liabilities arising from the sale of our products; however, there is no assurance that we will be able to maintain this insurance coverage on commercially reasonable terms or in adequate amounts or that this coverage will be sufficient to cover any losses arising from any claims related to our products or, if approved, product candidates. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business, including preventing or limiting the commercialization of our products and, if approved, product candidates.

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

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

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

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

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

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

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

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

The 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. Further, in February 2023, an agreement in principle was reached by the UK and EU, known as the Windsor Agreement, relating to post-Brexit trade issues in Northern Ireland, which seeks to simplify the supply of medicines between Great Britain and Northern Ireland and will mean the EU legislation may not apply in all cases in Northern Ireland. The new framework to be introduced by the Windsor Agreement is due to apply from January 1, 2025.

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 long-term 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. The UK government is instead consulting on the future regime for clinical trials in the UK. There is also a risk that the relevant authorities in the EU and the United Kingdom are unable to meet the additional administrative burden caused by Brexit and there have been considerable delays to the approval of clinical trials in recent months. Any delay in obtaining, or an inability to obtain, any marketing approvals or necessary modifications to such 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 was disruption to import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that, if repeated, 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 previous 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).

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") have been the subject of *inter partes* review proceedings brought by Moderna Therapeutics, Inc. ("Moderna") before the Patent Trial and Appeal Board of the USPTO ("PTAB"), whose decisions were subsequently reviewed by the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). The Federal Circuit ultimately (i) affirmed the PTAB's decision that upheld all claims of U.S. Patent No. 8,058,069; (ii) affirmed the PTAB's decision invalidating certain claims of U.S. Patent No. 9,364,435 but dismissed Moderna's appeal with respect to those claims that the PTAB upheld for lack of standing and (iii) affirmed the PTAB's decision invalidating all claims of U.S. Patent No. 9,404,127. 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 GmbH ("Genevant GmbH"), and Arbutus filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna and an affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19 (the "Moderna Action"). In November 2022, the District Court denied Moderna's partial motion to dismiss pursuant to 28 U.S.C. § 1498(a) ("§ 1498"). In March 2023, following the submission of a Statement of Interest in the case by the United States Government, the court reaffirmed its prior decision and again ruled that the complaint should not be partially dismissed on the basis of § 1498. In March 2022, Acuitas Therapeutics Inc. ("Acuitas") filed a lawsuit in the U.S. District Court for the Southern District of New York ("SDNY") against two of the Company's affiliates, Genevant and Arbutus, seeking a declaratory judgment that certain patents held by Arbutus and licensed by Genevant are not infringed by the manufacture, use, offer for sale, sale or importation into the 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, 2022, Genevant and Arbutus filed a motion to dismiss the first amended complaint for lack of a controversy and supporting brief. Briefing on this motion was completed in mid-November. On August 4, 2023, Acuitas voluntarily dismissed the action in the SDNY and re-filed a complaint in the U.S. District Court for the District of New Jersey (the "Acuitas Action"). On October 13, 2023, Genevant and Arbutus filed a motion to dismiss the re-filed complaint. On April 4, 2023, Genevant GmbH and Arbutus filed a lawsuit in the U.S. District Court for the District of New Jersey against Pfizer and BioNTech seeking damages for infringement of U.S. Patent Nos. 9,504,651, 8,492,359, 11,141,378, 11,298,320 and 11,318,098 in the manufacture and sale of COMIRNATY (the "Pfizer Action"). On July 10, 2023, Pfizer and BioNTech filed an answer. The Pfizer Action is proceeding and in the early stages of discovery.

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, the Pfizer 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, the trading price of our Common Shares could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on the price of our Common Shares.

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

- actual or anticipated fluctuations in our quarterly and annual financial results or the quarterly and annual financial results of companies perceived to be similar to it;

- changes in the market's expectations about operating results;

- our operating results failing to meet market expectations in a particular period;

- a Vant's operating results failing to meet market expectations in a particular period, which could impact the market prices of shares of a public Vant or the valuation of a private Vant, and in turn adversely impact the trading price of our Common Shares;

- receipt of marketing approval for a product or product candidate in one or more jurisdictions, or the failure to receive such marketing approval;

- the results of clinical trials or preclinical studies conducted by us and the Vants;

- changes in financial estimates and recommendations by securities analysts concerning us, the Vants or the biopharmaceutical industry and market in general;

- operating and stock price performance of other companies that investors deem comparable to us;

- changes in laws and regulations affecting our and the Vants' businesses;

- the outcome of litigation or other claims or proceedings, including governmental and regulatory proceedings, against us or the Vants;

- changes in our capital structure, such as future issuances of securities or the incurrence of debt;

- the volume of our Common Shares available for public sale and the relatively limited free float of our Common Shares;

- any significant change in our board of directors or management;

- sales of substantial amounts of our Common Shares by directors, executive officers or significant shareholders or the perception that such sales could occur; and

- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

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

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses are expected to increase from March 31, 2024, after which we will no longer qualify as 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.

Currently, due to our status as an "emerging growth company" and "smaller reporting company," we are able to take advantage of exemptions from various reporting and other requirements that are applicable to other public companies that are not "emerging growth companies," such as not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. However, because the market value of our Common Shares held by non-affiliates exceeded $700 million as of September 30, 2023 and we satisfy the other requirements of being a "large accelerated filer" pursuant to Rule 12b-2 under the Exchange Act, we will be deemed a "large accelerated filer" and will lose our current status as an "emerging growth company" as of March 31, 2024. As a result, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting beginning with our annual report for the fiscal year ending on March 31, 2024. We expect to incur significant compliance costs and expend substantial management efforts in order to comply with the additional compliance and reporting requirements. This could result in continuing uncertainty regarding compliance matters and higher costs associated with ongoing revisions to disclosure and governance practices. It is possible that compliance initiatives may not be sufficient to satisfy our obligations as a public company on a timely basis. In addition, 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 will no longer qualify as an "emerging growth company" and a "smaller reporting company" as of March 31, 2024 and, as a result, we will no longer be able to avail ourselves of certain reduced reporting requirements applicable to emerging growth companies or smaller reporting companies.

We are currently an "emerging growth company," as defined in the JOBS Act, and we have taken advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies," including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies, and we have elected to take advantage of the benefits of such extended transition period. As a result, our historical consolidated financial statements may not be comparable to those of companies that comply with such new or revised accounting standards.

Because the market value of our Common Shares held by non-affiliates exceeded $700 million as of September 30, 2023 and we satisfy the other requirements of being a "large accelerated filer" pursuant to Rule 12b-2 under the Exchange Act, we will be deemed a "large accelerated filer" and will lose our current status as an "emerging growth company" as of March 31, 2024. As a result of our loss of "emerging growth company" status, it is possible that investors will find our Common Shares less attractive in light of the fact that we have relied on certain of these exemptions. If some investors find our Common Shares less attractive as a result, there may be a less active trading market for our Common Shares and our share price may be more volatile. In addition, any failure to comply with these additional requirements in a timely manner, or at all, could have an adverse effect on our business and results of operations and could cause a decline in the price of our Common Shares.

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

We are subject to laws and regulations enacted by national, regional and local governments. In particular, we will be required to comply with certain SEC and other legal requirements. Compliance with, and monitoring of, applicable laws and regulations may be difficult, time consuming and

costly. Those laws and regulations and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with applicable laws or regulations, as interpreted and applied, could have a material adverse effect on our business and results of operations.

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

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

- a classified board of directors with staggered three-year terms;
- the ability of our board of directors to determine the powers, preferences and rights of preference shares and to cause us to issue the preference shares without shareholder approval; and
- requiring advance notice for shareholder proposals and nominations and placing limitations on convening shareholder meetings.

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

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

Our largest shareholders continue to hold a significant percentage of our Common Shares. As a result, these holders have the ability to substantially influence us and exert significant control through this ownership position and, in the case of certain holders, service on our board of directors. For example, these holders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. These holders' interests may not always coincide with our corporate interests or the interests of other shareholders, and they may exercise their voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Furthermore, our largest shareholders may from time to time have interests that differ from ours or from one another, and from time to time there may be disputes with or between such shareholders, which could be costly, time-consuming and divert management resources. So long as these holders continue to own a significant amount of our equity, they will continue to be able to strongly influence our decisions.

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

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

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

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

Sales of a substantial number of our Common Shares by us or certain of our existing large shareholders, or the perception that these sales could occur, could substantially decrease the market price of our Common Shares. Shares held by certain of our large shareholders have been registered for re-sale pursuant to a registration statement on Form S-3 and may also be sold pursuant to Rule 144 under the Securities Act, subject to certain restrictions (including restrictions applicable to affiliates in the case of shares held by persons deemed to be our affiliates). While certain of our significant shareholders are subject to contractual lock-up agreements as described under the heading "Lock-Up Agreements" in the description of our share capital attached as exhibit 4.5 to our annual report on Form 10-K filed with the SEC on June 28, 2023, these lock-up agreements are subject to significant limitations and expire by their terms on February 29, 2024. The market price of our Common Shares could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. This, in turn, could also make it more difficult for us to raise additional funds through future offerings of our Common Shares or other securities at prices that are attractive to us, or at all.

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

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

Because there are no 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.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have 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; (7) challenges to the transfer pricing policies related to our structure; (8) potential taxation under the OECD BEPS 2.0; and (9) potential limitation on tax attributes due to ownership changes (i.e. Internal Revenue Code 382 and 383) or expiration.

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

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

We believe that we will not be classified as a CFC for the taxable year ended March 31, 2023. However, our non-U.S. subsidiaries will be classified as CFCs for the taxable year ended March 31, 2023. For U.S. holders who hold 10% or more of the combined voting power or value of our Common Shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the IRS. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the combined voting power or value of our Common Shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing of our Common Shares.

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

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

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset. If we are a CFC (determined by disregarding certain downward attribution rules) and not publicly traded for the relevant taxable year, however, the test shall be applied based on the adjusted basis of our assets. Because our Common Shares should be considered to be "publicly traded" for the taxable 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, 2023, 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, 2023 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.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On November 9, 2023, the Company's Board of Directors appointed Mayukh Sukhatme to serve as a Class III director of the Company, effective as of that date. There are no arrangements or understandings between Dr. Sukhatme and any other persons pursuant to which he was selected as a director of the Company. There are no related person transactions (within the meaning of Item 404(a) of Regulation S-K) between Dr. Sukhatme and the Company or any of its subsidiaries.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1*#	Stock Purchase Agreement, by and among Roche Holdings, Inc., Roivant Sciences Ltd., Pfizer Inc. and Telavant Holdings, Inc., dated as of October 22, 2023				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

* Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any exhibits or schedules so furnished.

\# Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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: November 13, 2023

Exhibit 2.1

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

EXECUTION VERSION

STOCK PURCHASE AGREEMENT

BY AND AMONG

ROCHE HOLDINGS, INC.,

ROIVANT SCIENCES LTD.,

PFIZER INC.
(upon execution of and pursuant to the Joinder Agreement referred to herein),

AND

TELAVANT HOLDINGS, INC.

DATED AS OF OCTOBER 22, 2023

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STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "Agreement") is entered into as of October 22, 2023 (the "Effective Date"), by and among **Roche Holdings, Inc.**, a Delaware corporation (the "Buyer"), **Roivant Sciences Ltd.**, an exempted company limited by shares incorporated under the laws of Bermuda ("Rome"), and **Telavant Holdings, Inc.**, a Delaware corporation (the "Company"), and will subsequently be entered into by **Pfizer Inc.**, a Delaware corporation ("Paris") (collectively with Rome, the "Sellers"), pursuant to the Joinder Agreement referred to herein.

WHEREAS, (a) Rome is the direct beneficial owner and holder of record of 70,000,000 shares of Common Stock and 35,000,000 shares of Series A-1 Preferred Stock (collectively, the "Rome Company Shares") and (b) Paris is the direct beneficial owner and holder of record of 35,000,000 shares of Series A-2 Preferred Stock (the "Paris Company Shares" and, together with the Rome Company Shares, the "Company Shares");

WHEREAS, the Buyer wishes to purchase from the Sellers, and the Sellers wish to sell to the Buyer, all of the Company Shares upon the terms and subject to the conditions of this Agreement (such purchase and sale, together with all other transactions contemplated by this Agreement, the "Acquisition"); and

WHEREAS, the Parties desire to make certain representations, warranties, covenants and agreements in connection with, and to prescribe certain conditions to, the Acquisition as set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. For purposes of this Agreement, the following terms have the respective meanings set forth below:

"280G Gross-up Liabilities" means the aggregate amount of gross-up payments required to make Company Group Service Providers whole for any excise taxes and related penalties owed by the Company Group Service Providers under Section 4999 of the Code, as determined by KPMG LLP (the "280G Gross-up Payments"), and the employer portion of any employment or payroll Taxes related thereto.

"Accounting Principles" means the accounting principles, policies, procedures and methodologies set forth on Schedule A attached hereto.

"Accrued Bonus Obligations" means any unpaid cash incentive bonuses and commissions payable to any Company Group Employee pursuant to the terms of any Benefit Plan with respect to the portion of the year up to and including the Closing Date (the "Accrued Bonus Amounts"), and the employer portion of any employment or payroll Taxes related thereto.

"Action" means any judicial or administrative claim, action, charge, suit, arbitration, litigation or proceeding, by or before any Governmental Authority.

"Affiliate" means, with respect to any Person, any other Person which, at the time of determination, directly or indirectly (through one of more intermediaries), controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" (including correlative meanings, the terms "controlled by," "controlling" or "under common control") means (a) the direct or indirect ownership of 50% or more of the voting stock or other voting interests of the Person or (b) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body of the Person. Notwithstanding the foregoing, (w) no member of the Company Group shall be deemed to be an Affiliate of Rome or Paris, (x) Rome and Paris shall not be considered Affiliates of each other (y) Chugai Pharmaceutical Co., Ltd. shall not be deemed to be an Affiliate of Buyer and (z) Immunovant, Inc. and its Subsidiaries shall not be considered Affiliates of any member of the Rome Group.

"Antitrust Laws" means the Sherman Act of 1890, the Clayton Act of 1914, the Federal Trade Commission Act of 1914, the HSR Act and all other federal, state and foreign applicable Laws in effect from time to time that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade, or lessening of competition through merger or acquisition.

"Approved 280G Gross-up Liabilities" means the portion of the 280G Gross-Up Payments that Rome determines will be payable to the Company Group Service Providers, in an aggregate amount up to [***] (the "Approved 280G Gross-up Payments"), and the employer portion of any employment or payroll Taxes related thereto.

"Base Purchase Price" means $7,100,000,000.

"Biologic" means any composition of matter comprising proteins, nucleic acids, carbohydrates or a combination of these substances, including monoclonal antibodies (derivatives or fragments thereof), other binding proteins, peptide molecules, RNA molecules, DNA molecules, viruses, gene therapy vectors or genetically engineered cells, or any other article regulated by a Regulatory Authority as a biologic.

"BLA" means a Biologics License Application as described in 21 C.F.R. §601.2 or equivalent application in any applicable foreign jurisdiction.

"Business Day" means any day other than a Saturday, a Sunday or a day on which banks in New York City, New York; Hamilton, Bermuda; or London, United Kingdom are authorized or obligated by applicable Law to close.

"Business Material Adverse Effect" means any change, event, circumstance, occurrence, effect, state of facts or development that has had or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on the business, condition (financial or otherwise) or results of operations of the Company Group, taken as a whole; provided, however, that no change, event, circumstance, occurrence, effect, state of facts or development to the extent resulting or arising from any of the following matters shall be deemed, either alone or in combination, to constitute or contribute to, or be taken into account in determining whether there has been, or whether there would reasonably be expected to be, a "Business Material Adverse Effect": (i) changes generally affecting the U.S. or global economy or financial or securities markets, including changes in interest or exchange rates; (ii) the negotiation, execution, public announcement, pendency or consummation of the Acquisition and the identity of, or the effects of any facts and circumstances relating to, the Buyer, including any impact thereof on the suppliers, vendors, employees, service providers or other business relations of the Company Group (provided that this clause (ii) shall not apply to any representation or warranty to the extent the purpose of such representation or warranty is to address the consequences arising from the execution or delivery of this Agreement or the consummation of the Acquisition); (iii) (A) any act of war (whether or not declared), hostility, terrorism, riot, political unrest, calamity or crisis, or similar activities or events, (B) earthquake, landslide, tsunami, flood, hurricane, cyclone, tornado, volcanic activity, wildfire or other fire, drought, famine or other natural disaster, (C) epidemic, pandemic, endemic, disease or virus outbreak or public health emergency (including in respect of COVID-19) and (D) any continuation, escalation, worsening or other change in respect of any of the items or matters referenced in the foregoing clauses (A), (B) and (C); (iv) to the extent arising after the Effective Date and not resulting from knowing and intentional misconduct by the Rome Group, (A) any results, outcomes, data, adverse events, side effects or safety observations arising from any Clinical Trials being conducted by or on behalf of the Company Group relating to any Program Compound or Program Product or by any competitor of the Company Group (or the announcements thereof), (B) the determination by, or the delay of a determination by, the FDA or any other Governmental Authority, or any panel or advisory body empowered or appointed thereby, with respect to the hold (including clinical hold), acceptance, filing, designation, approval, clearance, non-acceptance, refusal to file, refusal to designate, non-approval, disapproval or non-clearance of any Program Compound or Program Product or any competitor's product candidates, (C) FDA approval (or other clinical or regulatory developments), market entry or threatened market entry of any product competitive with or related to any Program Compound or Program Product, or any guidance, announcement or publication by the FDA or other Governmental Authority relating to any Program Compound or Program Product or product of any competitor or (D) any manufacturing or supply chain disruptions or delays affecting any Program Compound or Program Product or developments relating to reimbursement, coverage or payor rules with respect to any Program Compound or Program Product (provided that this clause (iv) shall not apply to any representation or warranty to the extent the Person making such representation or warranty has committed Fraud with respect thereto); (v) any change generally in business, regulatory or other conditions in the industry in which the Company Group operates; (vi) any failure by the Company Group to meet any internal or published projections, forecasts or revenue or earnings predictions (it being understood that any change, event, circumstance, occurrence, effect, state of facts or development giving rise to or contributing to any such failure may be deemed, constitute or be taken into account in determining whether there has been, or there would reasonably be expected to be, a Business Material Adverse Effect, to the extent not otherwise excluded in this definition); (vii) any adoption, change, implementation, repeal, modification, reinterpretation or proposal of GAAP or any applicable Law by any Governmental Authority, in each case, after the Effective Date; (viii) any action taken or not taken by the Company Group or a Seller (A) at the Buyer's prior written request or with the Buyer's written consent or (B) in order to comply with the express terms of this Agreement; or (ix) to the extent [***] not resulting from knowing and intentional misconduct by the Rome Group, any results, outcomes, data, observations or any other information relating to or arising from any research, experiment, analysis or other testing (including any such testing with respect to chemistry, manufacturing and controls matters) conducted by or on behalf of the Buyer, the Sellers or any of their respective Affiliates, [***] (provided that this clause (ix) shall not apply to any representation or warranty to the extent the Person making such representation or warranty has committed Fraud with respect thereto), except, in the case of the foregoing clauses (i), (iii), (v) or (vii), to the extent that the Company Group, taken as a whole, is disproportionately and adversely affected thereby relative to other Persons operating in the industry in which the Company Group operates (in which case the incremental disproportionate adverse effect may be taken into account in determining whether there has been or would reasonably be expected to be a Business Material Adverse Effect).

"Buyer Material Adverse Effect" means any change, event, circumstance, occurrence, effect, state of facts or development that, individually or in the aggregate, would reasonably be expected to prevent or materially delay the ability of the Buyer to consummate the Acquisition.

"Calculation Time" means 11:59 p.m. (New York City time) on the day immediately prior to the Closing Date.

"Capital Stock" means the Common Stock and the Preferred Stock.

"CARES Act" means (a) the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) and any administrative or other guidance published with respect thereto by any Governmental Authority (including IRS Notices 2020-22 and 2020-65), or any other law or executive order or executive memorandum (including the Memorandum on Deferring Payroll Tax Obligations in Light of the Ongoing COVID-19 Disaster, dated August 8, 2020) intended to address the consequences of COVID-19 (in each case, including any comparable provisions of state, local or non-U.S. Law and including any related or similar orders or declarations from any Governmental Authority) and (b) any extension of, amendment, supplement, correction, revision or similar treatment to any provision of the CARES Act contained in the Consolidated Appropriations Act, 2021, H.R. 133.

"Clearances" means all consents, clearances, approvals, permissions, licenses, variances, exemptions, authorizations, acknowledgements, permits, nonactions, Orders and waivers to be obtained from, and all registrations, applications, notices and filings to be made with or provided to, any Governmental Authority or other Third Party in connection with the consummation of the Acquisition, including the expiration or termination of any waiting period (and any extensions thereof) under any applicable Laws.

"Clinical Trials" means any human clinical trials, including any Phase 1 Clinical Trials, Phase 2 Clinical Trials, Phase 3 Clinical Trials, Phase 4 Clinical Trials or variations or subsets of such trials.

"Closing Cash" means the aggregate amount of cash and cash equivalents held by the Company Group as of the Calculation Time, calculated in accordance with the Accounting Principles; provided that if any member of the Company Group uses any such cash or cash equivalents to pay any Indebtedness or Transaction Expenses or to repurchase or redeem any capital stock or other securities or to make any dividend or distribution, in each case, following such time and prior to immediately prior to the Closing, then Closing Cash shall be calculated as if such actions had been taken prior to such time. Closing Cash shall (a) exclude (i) the amount of any outstanding checks, outstanding drafts, outstanding wire transfers and outstanding debit transactions written or made for the accounts of any member of the Company Group that have not yet settled and (ii) the aggregate amount of all cash or cash equivalents that are not freely usable, distributable or transferable by the Company Group (including security or similar deposits, bond guarantees, amounts held as collateral in respect of outstanding letters of credit) and (b) include, to the extent not already reflected in the immediately preceding sentence, the amount of all cash subject to received checks, drafts, wire transfers and credit transactions written or made for the benefit of any member of the Company Group but not yet cleared.

"Closing Indebtedness" means any Indebtedness of the Company Group outstanding as of immediately prior to the Closing, calculated in accordance with the Accounting Principles.

"Closing Net Working Capital" means (a) the current assets of the Company Group, minus (b) the current liabilities of the Company Group, in each case as of the Calculation Time, in each case without duplication and without giving effect to the Acquisition, and calculated in accordance with the Accounting Principles, which current assets and current liabilities shall include only the line items set forth on Exhibit A attached hereto under the headings "Current Assets" and "Current Liabilities," respectively, and no other assets or liabilities; provided that in no event shall "Closing Net Working Capital" include (i) any amounts to the extent included in Closing Cash or Closing Indebtedness, (ii) amounts outstanding pursuant to intercompany accounts, arrangements, understandings or Contracts to be settled or eliminated at or prior to the Closing, or (iii) liabilities or payments that are expressly required to be paid at or following the Closing by a Seller or any of its Affiliates (excluding, for clarity, all members of the Company Group); and provided, further that "Closing Net Working Capital" (A) shall include all current Tax assets and liabilities (other than with respect to income Taxes) and (B) shall not include any income Tax assets or liabilities, deferred Tax assets or liabilities or any amounts included in the calculation of Transaction Expenses.

"Code" means the U.S. Internal Revenue Code of 1986.

"Commercialization" means activities directed to obtaining pricing and reimbursement approvals or marketing, promoting, branding, distributing, importing, exporting, using, offering for sale, selling or otherwise commercializing a product, including interacting with Regulatory Authorities regarding the foregoing.

"Common Stock" means the common stock, par value $0.01 per share, of the Company.

"Company Exclusively Licensed Intellectual Property" means all Company Licensed Intellectual Property that is exclusively licensed to any member of the Company Group, including, for the avoidance of doubt, the Intellectual Property exclusively licensed to Telavant under the Paris License Agreement.

"Company Group" means the Company and its Subsidiaries.

"Company Group Employee" means, as of any relevant time, each employee of the Company Group other than any officer who does not receive any compensation or benefits directly from any member of the Company Group.

"Company Group Service Provider" means, as of any relevant time, (a) each Company Group Employee, (b) each director or officer of the Company Group who receives compensation or benefits directly from any member of the Company Group and (c) each individual independent contractor who is a party to a written contract with any member of the Company Group to provide services to the Company Group.

"Company Intellectual Property" means the Company Owned Intellectual Property and Company Licensed Intellectual Property.

"Company Licensed Intellectual Property" means any and all Intellectual Property owned by a Third Party and licensed or sublicensed to any member of the Company Group or for which any member of the Company Group has obtained a covenant not to be sued.

"Company Owned Intellectual Property" means (a) any and all Intellectual Property that is owned (or purported to be owned) by any member of the Company Group and (b) the Telavant Trademarks. For purposes of this Agreement, "purported to be owned" means, with respect to any Intellectual Property, to be named the owner of record of any such Intellectual Property registered or recorded with a Governmental Authority for the purposes of establishing or providing notice of ownership of such Intellectual Property or to otherwise be claimed by any member of the Company Group as being owned or licensed by any member of the Company Group.

"Company RSU" means each restricted stock unit granted pursuant to the Company Stock Plan or otherwise (whether vested or unvested) that represents the right to receive payment in shares of Common Stock or an amount in cash equal to the fair market value of such shares of Common Stock.

"Company RSU Holder" means each Person holding any Company RSU as of immediately prior to the Closing.

"Company Stock Plan" means the Telavant Holdings, Inc. 2023 Equity Incentive Plan, as may be amended from time to time.

"Constitutive Documents" means the certificate of incorporation, certificate of formation, limited liability company agreement, bylaws or equivalent organizational documents of a Person.

"Contract" means any contract, commitment, agreement, instrument, obligation, subcontract, lease, license, sublicense, mortgage, indenture, bond, guaranty, promissory note, purchase order, undertaking or other legally binding arrangement or understanding, in each case, whether written or oral.

"Copyright" means any copyrights or copyrightable works, including all works for hire, all rights of authorship, use, publication, reproduction, distribution, performance, transformation, moral rights and rights of ownership of copyrightable works, all registrations, applications for registration and renewals of any of the foregoing anywhere in the world, and all rights to register and obtain renewals and extensions of registrations, together with all other interests accruing by reason of copyright Law anywhere in the world.

"Cover" or "Covered" means, with respect to any Patent, that any Manufacture, use, offer for sale, sale, importation or exportation of any product or practice of any method would infringe a claim of such Patent in the country in which such activity occurs absent a license thereto (or ownership thereof), and, in the case of a pending Patent application, that any Manufacture, use, offer for sale, sale, importation or exportation of any product or practice of any method would infringe a pending claim thereof, assuming that such pending claim had been issued.

"COVID-19" means SARS-CoV-2 or COVID-19, and any evolutions thereof or related or associated epidemics, pandemic or disease outbreaks.

"COVID-19 Measures" means any quarantine, "shelter in place," "stay at home," workforce reduction, social distancing, shut down, closure, sequester, safety or similar Laws, guidelines or recommendations promulgated by any Governmental Authority, including the Centers for Disease Control and Prevention and the World Health Organization, in each case, in connection with or in response to COVID-19 (including the CARES Act, together with any administrative or other guidance published with respect thereto by any Governmental Authority).

"D&O Insurance" has the meaning set forth in Section 7.11(b).

"Data Protection Laws" means all applicable Laws, including the relevant Healthcare Laws, relating to the access, collection, use, processing, storage, sharing, distribution, transfer, disclosure, security, destruction or disposal of Personal Data, data privacy, data security or data breach notification.

"Data Requirements" means all of the following to the extent relating to the access, collection, use, processing, storage, sharing, distribution, transfer, disclosure, security, destruction or disposal of any Personal Data or any sensitive or confidential information or data (whether in electronic or any other form or medium) with respect to the Program Business by any member of the Company Group: (a) the Rome Group's own published privacy policies applicable to the Program Business; (b) all Data Protection Laws; (c) industry standards and certifications binding on any member of the Company Group with respect to the Program Business (including, to the extent applicable, the Payment Card Industry Data Security Standards (PCI-DSS)) and (d) contractual obligations of any member of the Company Group.

"Development" means Pre-Clinical Development and clinical drug development activities reasonably relating to the development of a compound or product and submission of information regarding a compound or product to a Regulatory Authority in connection therewith, including Clinical Trials (including pre- and post-Regulatory Approval studies and statistical analysis), but excluding Commercialization activities. When used as a verb, "Develop" means to engage in Development.

"Development Plan" means the written Development plan that sets forth the anticipated Development activities to be performed by or on behalf of the Company Group related to any Program Compound or Program Product during the Pre-Closing Period, including a budget therefor, as may be amended from time to time by the Company Group in accordance with the terms of this Agreement. The Development Plan as of the Effective Date is attached hereto as Exhibit B.

"DOJ" means the United States Department of Justice.

"EMA" means the European Medicines Agency.

"Encumbrance" means any charge, lien, mortgage, hypothecation, deed of trust, pledge, charge, security interest, easement, servitude, encroachment, license or other similar encumbrance (any action of correlative meaning, to "Encumber").

"Environmental Claim" means any claim, action, cause of action, suit, proceeding, investigation, information request, order, demand or notice (written or oral) by any Person alleging actual or potential liability (including actual or potential liability for investigatory costs, cleanup costs, governmental response costs, natural resources damages, property damages, personal injuries, attorneys' fees, fines or penalties or corrective actions) arising out of, based on, resulting from or relating to (a) the presence, release or threatened release into the environment, of, or exposure to, any Materials of Environmental Concern at any location, now or in the past or (b) conditions, facts or circumstances forming the basis of any violation, or alleged violation, of any Environmental Law.

"Environmental Laws" means all Laws relating to pollution, human and worker health or safety, or protection of the environment (including indoor and ambient air, surface water, ground water, land surface or subsurface strata, and natural resources), including Laws relating to (a) emissions, discharges, releases or threatened releases of, or exposure to, Materials of Environmental Concern, (b) the manufacture, processing, distribution, marketing, sale, use, treatment, generation, storage, containment (whether above ground or underground), disposal, transport or handling of Materials of Environmental Concern, (c) recordkeeping, notification, disclosure and reporting requirements regarding Materials of Environmental Concern, (d) endangered or threatened species of flora and fauna (including fish, wildlife and plants), and the management or use of natural resources, (e) the preservation of the environment or mitigation of adverse effects on or to human health or the environment or (f) emissions or control of greenhouse gases.

"Equity Securities" means (a) any capital stock or share capital of, other voting securities of, other equity, membership or other ownership interest in any Person, (b) any securities (including debt securities) directly or indirectly convertible into, or exchangeable or exercisable for, any capital stock or share capital of, other voting securities of, other equity, membership or other ownership interest in any Person, (c) any rights, warrants or options (including exchange rights, put rights and call rights) directly or indirectly to subscribe for or to purchase any capital stock or share capital of, other voting securities of or other equity, membership or other ownership interest in, any Person, or to subscribe for or to purchase any securities (including debt securities) convertible into, or exchangeable or exercisable for, any capital stock or share capital of, other voting securities of or other equity, membership or other ownership interest in, any Person or (d) any share appreciation rights, phantom share rights, other rights the value of which is linked to the value of any securities or interests referred to in clauses (a) through (c) above or other similar rights.

"ERISA" means the Employee Retirement Income Security Act of 1974.

"ERISA Affiliate" means any Person that, at any relevant time, is treated as a single employer with any member of the Company Group pursuant to Section 414(b), (c), (m) or (o) of the Code or Section 4001(b) of ERISA.

"Estimated Purchase Price" means an amount equal to the Base Purchase Price (a) plus the amount of Estimated Closing Cash, (b) plus the amount of the Estimated Net Working Capital Adjustment Amount, (c) less the Estimated Closing Indebtedness and (d) less the amount of all Estimated Transaction Expenses.

"FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act.

"FDA" means the U.S. Food and Drug Administration.

"Filing" means any registration, petition, statement, application, schedule, form, declaration, notice, notification, report, submission or other filing.

"Fraud" means, with respect to a Party, an actual and intentional fraud with respect to any representation or warranty made by such Party set forth in Article III, Article IV or Article V, as applicable. For the avoidance of doubt, Fraud does not include (a) constructive fraud or other similar fraud claims based on constructive knowledge, negligence, misrepresentation or any similar theory or (b) equitable fraud, promissory fraud, unfair dealings fraud or any other tort (including fraud) based on negligence or recklessness or any similar theory.

"FTC" means the United States Federal Trade Commission.

"Fully Diluted Share Number" means the sum (without duplication) of (a) the aggregate number of shares of Common Stock issued and outstanding as of immediately prior to the Closing, (b) the aggregate number of shares of Common Stock issuable upon conversion of all shares of Preferred Stock issued and outstanding as of immediately prior to the Closing and (c) the aggregate number of shares of Common Stock issuable upon the settlement of all Company RSUs issued and outstanding as of immediately prior to the Closing.

"Fundamental Representations" means the representations and warranties of the Sellers and the Company in (a) Sections 3.1 and 3.2(a) and (b) Sections 4.1, 4.2, 4.3(a), 4.3(b), the last sentence of 4.4(c), 4.6(b) (solely with respect to the Paris License Agreement), 4.16(g), 4.16(i), 4.20(e), 4.23 and 4.26.

"GCP" means the applicable then-current FDA 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 and 58, and all analogous guidelines promulgated by the EMA or the ICH, as applicable.

"GLP" means the applicable then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by other applicable Regulatory Authorities, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

"GMP" means the applicable then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and 21 C.F.R. Parts 210, 211 and 600-680, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other applicable Regulatory Authorities, as they may be updated from time to time.

"Governmental Authority" means any (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature, (b) international, supranational, transnational, multinational, federal, state, local, municipal, foreign or other government, agency or authority or (c) governmental or quasi-governmental authority of any nature (including any governmental or non-governmental self-regulating, division, department, agency, Regulatory Authority, commission, instrumentality, organization, unit or body and any court, arbitral body or other tribunal).

"Governmental Authorizations" means all licenses, permits (including insurance permits), variances, waivers, orders, registrations, consents, certificates, certifications, clearances, concessions, grants, approvals, franchises and other authorizations and approvals of or by a Governmental Authority required (a) with respect to the Parties, to perform their respective obligations hereunder and (b) to carry on the Program Business or the business of the Company Group.

"Healthcare Laws" means any applicable Laws (a) pertaining to the research, Development, testing, production, Manufacture, transfer, storing, distribution, approval, labeling, marketing, pricing, Third Party reimbursement or sale and other Commercialization of pharmaceutical products and Biologics, (b) governing the development, conduct, monitoring, patient informed consent, auditing, analysis and reporting of Clinical Trials and (c) all regulations promulgated pursuant to (a) and (b) and analogous or similar applicable Laws governing the testing, approval, manufacturing, marketing, sale and other Commercialization of pharmaceutical products and Biologics and relationships with payors, patients and healthcare professionals, including the FD&C Act, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a) and HIPAA.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and the Health Information and Technology for Economic and Clinical Health Act of 2009.

"HSR Act" means the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976.

"ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"IND" means an Investigational New Drug Application under 21 C.F.R. Part 312 in the United States or similar clinical trial application in other countries.

"Indebtedness" of any Person means, without duplication, (a) all indebtedness of such Person for borrowed money (including all obligations for principal, interest, penalties, fees, expenses, breakage costs, prepayment premiums or penalties incurred in connection with the repayment of such borrowed money and bank overdrafts thereunder), (b) all obligations of such Person evidenced by debt securities, bonds, debentures, notes or similar instruments, (c) all obligations of such Person under conditional sale or other title retention agreements relating to property or assets purchased by such Person, (d) all Indebtedness of others secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Encumbrance (other than Permitted Encumbrances or Permitted Licenses) on property owned or acquired by such Person, whether or not the obligations secured thereby have been assumed (calculated, in the case of Indebtedness for which recourse is limited solely to the property subject to the applicable Encumbrance, as an amount equal to the lesser of (i) the value (as determined in good faith by the Company) of the property of such Person subject to such Encumbrance securing such Indebtedness and (ii) the amount of such Indebtedness), (e) all guarantees by such Person of Indebtedness of others, (f) the capitalized amount of all capital lease obligations of such Person (excluding, for the avoidance of doubt, any operating leases), (g) all reimbursement obligations of such Person as an account party in respect of letters of credit, performance bonds and banker's acceptances (to the extent drawn), (h) all accrued and unpaid income Taxes of the Company Group with respect to all Pre-Closing Tax Periods, taking into account and netting out Tax credits and other Tax assets of any member of the Company Group, including all Transaction Tax Deductions, to the extent such credits and assets would actually reduce the tax liability accrued hereunder (which amount under this clause (h) shall not be less than zero for any jurisdiction in which such Taxes are accrued for any Pre-Closing Tax Period), (i) any net cash payment obligations of such Person under any currency swaps, forward contracts, currency or other derivative or hedging arrangements of such Person, in each case to the extent payable as a result of the consummation of the Acquisition, (j) any declared but unpaid dividends, or other distributions or loans payable by such Person to its equityholders or Affiliates (excluding those set forth in Section 7.8 of the Company Disclosure Schedule), (k) to the extent not settled or eliminated prior to Closing, any amounts owed by any member of the Company Group to any Affiliate of the Sellers that is not a member of the Company Group and (l) subject to clause (v) of the immediately following sentence, the maximum gross amount of any "earn-out" or similar obligation; provided, however, that for clarity, Indebtedness shall exclude any Transaction Expenses and any amounts included (or required to be included) in the Net Working Capital Adjustment Amount. For the avoidance of doubt, Indebtedness shall not include (i) any trade credit or trade payables, (ii) any Indebtedness incurred or arranged by the Buyer and its Affiliates (and subsequently assumed or guaranteed by the Company Group) on or after the Closing Date, (iii) any obligations or liabilities under any Contract between the Company Group, on the one hand, and the Buyer or any of its Affiliates, on the other hand, (iv) any Intercompany Obligations and (v) any milestone, royalty or other deferred or contingent payment obligations, including any of the foregoing under the Paris License Agreement, any of [***] or any Contract with any contract manufacturing organization or contract research organization entered into in the Ordinary Course.

"Intellectual Property" means any and all of the following in any jurisdiction throughout the world and all rights associated therewith: (a) Patents and other indicia of ownership of an invention recognized or issued by or filed with any Governmental Authority; (b) inventions, discoveries and other Know-How, including articles of manufacture, business methods, compositions of matter, improvements, machines, methods and processes and new uses for any of the preceding items; (c) Trademarks; (d) published and unpublished works of authorship, including audiovisual works, collective works and Copyrights; (e) improvements, derivatives, modifications, enhancements, revisions and releases relating to any of the foregoing; (f) instantiations of any of the foregoing in any form and embodied in any media; (g) software (including source code, executable code, systems, network tools, data, databases, applications, firmware and all related documentation); (h) other intellectual property and proprietary rights; (i) rights to claim priority to, and to collect royalties and proceeds in connection with, any of the foregoing; and (j) rights to sue and recover and retain damages, costs and attorneys' fees for past, present or future infringement, misappropriation or violation of any of the foregoing.

"Intercompany Obligations" means all intercompany accounts, all intercompany Indebtedness and all other intercompany obligations between either Seller or any of its Affiliates, on the one hand, and any member of the Company Group, on the other hand.

"International Plan" means a Benefit Plan maintained primarily for employees and former employees located outside of the United States.

"Joinder Agreement" means the Joinder Agreement, substantially in the form attached hereto as Exhibit C, with such modifications thereto as the Buyer and Rome may agree.

"Know-How" means all confidential and proprietary commercial, technical, scientific and other data, results, know-how and information, trade secrets, inventions, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, knowledge, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs and specifications (including biological, chemical, structural, pharmacological, toxicological, clinical, safety, assay, method of screening, study designs and protocol and related know-how and trade secrets, and manufacturing data, non-clinical information, pre-clinical and clinical data, specifications of ingredients, manufacturing processes, formulation, specifications, sourcing information, quality control and testing procedures and related know-how and trade secrets), in all cases, whether or not confidential, proprietary, reduced to practice, patented or patentable, in written, electronic or any other form now known or hereafter developed.

"Law" means local, state, supranational, federal, national, regional, municipal, provincial or international statute, law, act, constitution, ordinance, code, rule, treaty, regulation, common law or other legal requirement.

"Liabilities" means all liabilities and obligations of every kind and nature, whether accrued, direct or indirect, fixed or contingent, mature or inchoate, known or unknown, reflected on a balance sheet or otherwise, including those arising under any Law or any judgment of any court of any kind or any award of any arbitrator of any kind, and those arising under any Contract, commitment or undertaking.

[***]

"MAA" means a marketing authorization application, including a BLA, to market a pharmaceutical product or Biologic in any country or group of countries, as defined in the applicable Laws and filed with the Regulatory Authority of a given country or group of countries.

"Manufacturing" means all activities directed to making, sourcing of necessary raw materials, manufacturing, producing, processing, packaging, labeling, finishing, quality assurance testing, shipping, holding (prior to distribution) and release of a product (or any component of such product). When used as a verb, "Manufacture" means to engage in Manufacturing.

"Materials of Environmental Concern" means any hazardous, acutely hazardous, or toxic substance or waste or any other substance, in each case, as defined by or regulated under Environmental Laws, including the federal Comprehensive Environmental Response, Compensation and Liability Act and the federal Resource Conservation and Recovery Act.

[***]

"Most Recent Balance Sheet Date" means September 30, 2023.

[***]

"Net Working Capital Adjustment Amount" means an amount (which may be a positive or negative number) equal to (a) the Closing Net Working Capital minus (b) the Target Net Working Capital.

"Order" means, with respect to any Person, any judgment, decision, writ, decree, award, consent decree, injunction, ruling or order of any federal, state, local or other domestic or foreign court or Governmental Authority or arbitrator (in each case, whether temporary, preliminary or permanent) that, in each case, is binding on such Person or its property under applicable Laws.

"Ordinary Course" means the ordinary course of the Company Group's business.

"Paris License Agreement" means that certain License and Collaboration Agreement, dated as of November 21, 2022, by and between Paris, Rome and Telavant.

"Paris Transaction Agreements" means the (a) Voting Agreement, dated as of November 21, 2022, among Rome, Paris and the Company, (b) Investor Rights Agreement, dated as of November 21, 2022 among Rome, Paris and the Company (the "Investor Rights Agreement"), (c) Right of First Refusal and Co-Sale Agreement, dated as of November 21, 2022 among Rome, Paris and the Company (the "ROFR and Co-Sale Agreement") and (d) the Commitment Letter, dated as of November 21, 2022, by and between Rome and the Company (the "Equity Commitment Letter").

"Parties" means Rome, Paris (solely upon the execution and delivery of the Joinder Agreement and solely with respect to the sections of this Agreement specified therein), the Company and the Buyer.

"Patents" means (a) all patents and patent applications (provisional and non-provisional) anywhere in the world, including PCT applications, (b) all divisionals, continuations, continuations in-part thereof, or any other patent application claiming priority, or entitled to claim priority, directly or indirectly, to (i) any such patents or patent applications or (ii) any patent or patent application from which such patents or patent applications claim, or are entitled to claim, direct or indirect priority, and (c) all patents issuing on any of the foregoing anywhere in the world (including from PCT applications), together with all registrations, reissues, re-examinations, patents of addition, utility models or designs, renewals, substitutions, revisions, provisionals, supplemental protection certificates, inventors' certificates and all disclosures, or extensions of any of the foregoing and counterparts thereof anywhere in the world.

"Per Share Value" means an amount equal to the quotient of (a) an amount equal to the Estimated Purchase Price divided by (b) the Fully Diluted Share Number.

"Per Share Milestone Payment Amount" means, if applicable, with respect to the Milestone Payment payable under Exhibit G, an amount equal to the quotient of (a) an amount equal to (i) the Milestone Payment, less (ii) the aggregate amount of the employer portion of any employment or payroll Taxes required to be paid in respect of the portion of the Milestone Payment allocable to Company RSUs, whether or not such employment or payroll Taxes are due and payable at the time of payment of the underlying compensatory obligation, divided by (b) the Fully Diluted Share Number.

"Permitted Encumbrances" means the following: (a) Encumbrances expressly disclosed in the Company's balance sheet as of the Most Recent Balance Sheet Date; (b) Encumbrances for Taxes (i) not yet due or payable or (ii) that are being contested in good faith by appropriate proceedings and, if so contested, for which adequate reserves have been established in accordance with GAAP; (b) Encumbrances for assessments and other governmental charges or Encumbrances of landlords, carriers, warehousemen, mechanics and repairmen incurred in the Ordinary Course, in each case (i) for sums not yet due and payable or (ii) due but not delinquent or (iii) being contested in good faith by appropriate proceedings and, in the case of this clause (iii), for which adequate accruals or reserves have been established on the books and records of the Company Group in accordance with GAAP; (d) security given in the Ordinary Course to any public utility or Governmental Authority; (e) Encumbrances in the nature of zoning restrictions, easements, rights or restrictions of record on the use of real property if the same do not materially detract from the value of the property encumbered thereby or materially impair the use of such property in the business of the Company Group; (f) Encumbrances that do not materially interfere with the use or operation of the property subject thereto and (g) Permitted Licenses.

"Permitted License" means any non-exclusive license of Intellectual Property granted by any member of the Company Group in the Ordinary Course in furtherance of the Development or Manufacturing activities of the Company Group to be performed on behalf of any member of the Company Group by a services provider; provided that the agreement under which such non-exclusive license is granted (a) does not grant the applicable licensee any Commercialization rights with respect to any of the Program Products or any Intellectual Property licensed thereunder, (b) does not include any royalty or other similar contingent payment obligation of any member of the Company Group based upon the Manufacture, use or sale of services, processes or products or the grant of sublicenses under such license for the Manufacture, use or sale of services, processes or products, and (c) shall not cease to be valid and binding and in full force and effect on terms identical in all material respects to those currently in effect as a result of the consummation of the transactions contemplated by this Agreement, nor shall the consummation of such transactions constitute a material breach or default under such license or otherwise give the counterparty thereto or any other Person a right to terminate such license.

"Person" means any individual, a limited liability company, a joint venture, a corporation, a company, a partnership, an association, a business trust, a trust, a Governmental Authority or any other entity or organization, whether or not a legal entity.

"Personal Data" means all data or other information (a) that can identify an individual or, in combination with any other information or data available to any member of the Company Group, is capable of identifying an individual or (b) that is otherwise considered "personally identifiable information," "personal information," "individually identifiable health information," "personal data" or the like under any applicable Data Protection Laws.

"Phase 1 Clinical Trial" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(a) and is intended to determine metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses and, if possible, to gain early evidence of efficacy, or any comparable trial under applicable Laws.

"Phase 2 Clinical Trial" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(b) and intended to explore a variety of doses, dose responses and durations of effect, and to generate data on side effects and clinical efficacy for a particular indication or indications in a target patient population, or any comparable trial under applicable Laws.

"Phase 3 Clinical Trial" means a human clinical trial of a product designed to satisfy the requirements of 21 C.F.R. § 312.21(c) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed and (c) support Regulatory Approval for such product, or any comparable trial under applicable Laws.

"Phase 4 Clinical Trial" means a human clinical trial, or other test or study, of a product for an indication that is commenced after receipt of the initial Regulatory Approval for such indication in the country for which such trial is being conducted and that is conducted within the parameters of the Regulatory Approval for the product for such indication (and which may include investigator-sponsored clinical trials), including a clinical trial conducted due to the request or requirement of a Regulatory Authority or as a condition of a previously granted Regulatory Approval.

"Pre-Clinical Development" means activities relating to the discovery, research and pre-clinical development of a compound or product, including toxicology, pharmacology and other discovery, optimization and pre-clinical efforts, test method development and stability testing, Manufacturing process development, formulation development, delivery system development, and quality assurance and quality control development, but excluding Clinical Trials (including pre- and post-Regulatory Approval studies and statistical analysis) and Commercialization activities.

"Pre-Closing Tax Period" means any Tax Period ending on or before the Closing Date and the portion of any Straddle Period ending on the Closing Date.

"Preferred Stock" means the Series A-1 Preferred Stock and the Series A-2 Preferred Stock.

"Program Business" means the business of the Company Group as conducted by the Company Group as of the Effective Date and as of immediately prior to the Closing.

"Program Compound" means any TL1A Antibody that is Covered by any Patent or incorporates or embodies any Know-How that is owned by or licensed to any member of the Company Group. A complete list of Program Compounds, as of the Effective Date, is set forth in Section 1.1 of the Company Disclosure Schedule.

"Program Product" means any pharmaceutical composition, preparation or product that constitutes, incorporates, comprises, or contains any Program Compound, alone or in combination with one or more other active ingredients (that are not Program Compounds), whether co-formulated or co-packaged, in each case in any presentation, form or formulation (including in any dosage strength) for any and all uses.

"Pro Rata Portion" means, with respect to each Seller, an amount equal to the quotient of (a) the sum of (i) the aggregate number of shares of Common Stock held by such Seller as of immediately prior to the Closing plus (ii) the aggregate number of shares of Common Stock issuable upon conversion of all shares of Preferred Stock held by such Seller as of immediately prior to the Closing divided by (b) the sum (without duplication) of (i) the aggregate number of shares of Common Stock issued and outstanding as of immediately prior to the Closing and held by the Sellers and (ii) the aggregate number of shares of Common Stock issuable upon conversion of all shares of Preferred Stock issued and outstanding as of immediately prior to the Closing and held by the Sellers and disregarding any conversion of Company RSUs such that the sum of the Pro Rata Portions held by Rome and Paris shall always equal 100%.

"Protected Health Information" shall have the same meaning set forth in 45 C.F.R. §160.103.

"Purchase Price" means an amount equal to the Base Purchase Price (a) plus the amount of Closing Cash, (b) plus the amount of the Net Working Capital Adjustment Amount, (c) less the amount of Closing Indebtedness and (d) less the amount of all Transaction Expenses.

"Registered Company Intellectual Property" means any and all Company Owned Intellectual Property or Company Exclusively Licensed Intellectual Property that is the subject of an application, certificate, filing, registration or other document issued by, filed with or recorded by, any Governmental Authority in any jurisdiction, including internet domain name registrations, websites and social media handles owned or exclusively licensed by the Company Group in the conduct of its business.

"Regulatory Approvals" means, with respect to a country or region, any approvals, clearances, authorizations, registrations, certifications, licenses and permits granted by the relevant Governmental Authority necessary in order to import, distribute, market and sell a pharmaceutical product in such country or region, including any BLAs and MAAs (but excluding pricing and reimbursement approvals).

"Regulatory Authority" means, with respect to a jurisdiction, any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, subdivision, instrumentality, official, bureau, commission, council or other governmental authority with responsibility for granting any Regulatory Approvals with respect to any pharmaceutical or biologic product.

"Regulatory Filings" means, collectively, any and all applications, filings, submissions, approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, permits, notifications and authorizations (including MAAs and other Regulatory Approvals) or waivers with respect to the Development, Manufacture, Commercialization or other exploitation of a pharmaceutical product (including any compound, Biologic or product) made to or received from any Regulatory Authority in a given country, including any IND or BLA.

"Retained Severance Obligations" means the sum of (a) the aggregate amount for all Terminated Employees of, with respect to each such Terminated Employee, any excess of (i) such Terminated Employee's Contractual Cash Severance over (ii) the Section 7.10(a) Cash Severance and (b) any excess of (i) the sum of (A) the aggregate Severance Obligations for the New Hires and (B) the employer portion of any employment or payroll Taxes related thereto over (ii) [***].

"Rome Group" means Rome and its Subsidiaries (including, prior to the Closing, the Company Group); provided that Immunovant, Inc. and its Subsidiaries shall not be included in the Rome Group.

"Rome's Knowledge" or the "Knowledge of Rome" means, the actual knowledge, upon reasonable inquiry of their respective direct reports, of [***].

"Securities Act" means the Securities Act of 1933.

"Seller Material Adverse Effect" means any change, event, circumstance, occurrence, effect, state of facts or development that, individually or in the aggregate, would reasonably be expected to prevent or materially delay the ability of any Seller to consummate the Acquisition.

"Series A-1 Preferred Stock" means Series A-1 Preferred Stock, par value $0.01 per share, of the Company.

"Series A-2 Preferred Stock" means Series A-2 Preferred Stock, par value $0.01 per share, of the Company.

"Services Agreement" means that certain Services Agreement, dated as of November 21, 2022, by and among Roivant Sciences, Inc., the Company and Telavant.

"Straddle Period" means any Tax Period beginning before the Closing Date and ending after the Closing Date.

"Subsidiary" means, with respect to any Person, any other Person as to which it owns, directly or indirectly, or otherwise controls, more than 50% of the voting shares or other similar interests, or any partnership or limited liability company of which such Person is a general partner or managing member. Notwithstanding the foregoing, Chugai Pharmaceutical Co., Ltd. shall not be deemed to be a Subsidiary of Buyer.

"Target Net Working Capital" means [***].

"Tax" means all income, capital gains, gross income, gross receipts, sales, use, ad valorem, franchise, capital, profits, license and other withholding, employment, social security, payroll, transfer, conveyance, documentary, stamp, property, value added, customs duties, minimum taxes, estimated and any other taxes, fees, charges, levies, excises, duties or assessments in the nature of a tax, together with additions to tax or additional amounts, interest and penalties relating thereto that may be imposed by the U.S. federal government or any state, local or non-U.S. government.

"Tax Authority" means the Internal Revenue Service and any state, local or non-U.S. Governmental Authority responsible for the assessment, collection, imposition or administration of any Taxes.

"Tax Package" means (a) pro forma U.S. federal, state and local combined, consolidated, affiliated, unitary or similar Tax Returns relating to the operations of the Company Group (including all associated workpapers) for the Tax Period of the Company Group ending on the Closing Date and (b) any additional information relating to the operations of the Company Group for the Tax Period including the Closing Date for the jurisdictions listed in Section 4.10(f) of the Company Disclosure Schedule in the case of state and local Tax Returns and such other jurisdictions as Rome and Buyer may reasonably agree that is reasonably necessary to prepare and file any applicable Tax Return required to be filed by Rome; provided that in no event shall the Tax Package include any information related to the operations of the Buyer or any of its Affiliates (other than such information related to the operations of the Company Group covered by clauses (a) and (b) of this definition).

"Tax Period" means any period prescribed by any Governmental Authority for which a Tax Return is required to be filed or a Tax is required to be paid.

"Tax Return" means any and all returns, reports, information returns, declarations, statements, claims for refund or other written information with respect to any Tax which is supplied to or required to be supplied to any Tax Authority, including any and all attachments, amendments and supplements thereto.

"Tax Sharing Agreement" means any agreement or arrangement, including any Tax sharing, allocation, indemnification, reimbursement, receivables or similar agreement entered into prior to the Closing, binding any member of the Company Group that provides for the allocation, apportionment, sharing or assignment of any Tax liability or Tax benefit, in each case other than agreements or arrangements entered into in the Ordinary Course that do not relate primarily to Taxes.

"Telavant" means Telavant, Inc., a Delaware corporation.

"Telavant Trademarks" means (a) any Trademark that contains the name or mark "Telavant" and (b) any other Trademarks that are similar to, or a variation or derivation of, "Telavant" (including all translations, abbreviations and adaptations thereof and combinations therewith and any Trademark derived from, confusingly similar to or including any of the foregoing), in each case that are owned by any member of the Rome Group.

"Third Party" means any Person other than the Buyer, the Sellers (but with respect to Paris, only upon the execution and delivery of the Joinder Agreement, until which point it shall be deemed a Third Party), the members of the Company Group and their respective Affiliates.

"TL1A" means [***].

"TL1A Antibody" means any antibody or antigen binding portion thereof that is intended to bind to, affect, induce an inhibition, activation, disruption or other modulation of, or is otherwise directed to, TL1A.

"Trademark Assignment Agreement" means the trademark assignment agreement to be entered into by and between Roivant Sciences GmbH and the Company, substantially in the form attached hereto as Exhibit F, pursuant to which Roivant Sciences GmbH will transfer and assign to the Company all of the Telavant Trademarks owned by the Rome Group as of immediately prior to the Closing.

"Trademarks" means any and all trademarks, service marks, trade dress, trade names, logos, slogans, words, names, symbols, designs, corporate names, internet domain names, social media handles and accounts, doing business designations, and all other indicia of origin (whether or not registered), and all registrations, applications for registration and renewals of any of the foregoing anywhere in the world, and all goodwill associated with any of the foregoing.

"Transaction Expenses" means (a) (i) all fees, costs and expenses payable to legal counsel or to any financial advisor, accountant, consultant, auditor, expert or other similar professional Person who performed services for or on behalf of the Company Group in connection with the negotiation, preparation, execution and consummation of this Agreement, other agreements and arrangements prepared in connection herewith and the Acquisition or the process by which Rome or its Representatives solicited, discussed or negotiated strategic alternatives with respect to the Company Group or the Program Business and (ii) all brokers' or finders' fees payable in connection with the Acquisition, in the case of each of clauses (i) and (ii), that were incurred (and whether or not yet invoiced), by the Company Group prior to the Closing and remain unpaid as of immediately prior to the Closing (the amounts set forth in this clause (a), the "Specified Transaction Expenses"), (b) the employer portion of any employment or payroll Taxes related to the Closing Company RSU Consideration, whether or not such employment or payroll Taxes are due and payable at the time of payment of the underlying compensatory obligation, in the case of clause (b), other than amounts that have been paid prior to the Closing and (c) the Retained Severance Obligations and the Accrued Bonus Obligations; provided, however, that in no event shall Transaction Expenses include any amounts to the extent included (or required to be included) in Closing Indebtedness or in the Net Working Capital Adjustment Amount.

"Transaction Tax Deductions" means, without duplication and regardless of by whom paid, the aggregate amount of Tax deductions to the extent deductible by any member of the Company Group at a "more likely than not" (or higher) comfort level in a Pre-Closing Tax Period with respect to (i) any and all stay bonuses, sale bonuses, change in control payments, retention payments, severance payments, synthetic equity payments or similar payments made or to be made by the Company Group in connection with or resulting from the Closing (or included as a liability in Closing Net Working Capital or Closing Indebtedness), (ii) all fees, expenses and interest (including amounts treated as interest for U.S. federal income Tax purposes), original issue discount, accelerated, deferred or unamortized debt financing costs, breakage fees, tender premiums, consent fees, redemption, retirement or make whole payments, defeasance in excess of par or similar payments incurred in respect of the Indebtedness in connection with the Closing (or included as a liability in Closing Net Working Capital), (iii) all fees, costs and expenses incurred by the Company Group in connection with or incident to this Agreement and the transactions contemplated hereby (or included as a liability in Closing Net Working Capital or Closing Indebtedness), including any such legal, accounting and investment banking fees, costs and expenses, (iv) any employment Taxes with respect to the amounts set forth in the foregoing clause (i) and (v) any Transaction Expenses not otherwise included in the foregoing clauses (i) through (v). The Parties shall apply the safe harbor election set forth in Internal Revenue Service Revenue Procedure 2011-29 to determine the amount of any success-based fees for purposes of clause (iii) above.

"Willful Breach" means, with respect to any agreement or covenant, a material breach that is the consequence of an action or omission by the breaching party with actual knowledge that such action or omission is, or would reasonably be expected to be or result in, a breach of such agreement or covenant.

1.2 Terms Defined Elsewhere in This Agreement . For purposes of this Agreement, the following terms have meanings set forth in the sections indicated:

Term	Section	Term	Section
280G Gross-up Payments	Section 1.1	Indemnified Party	Section 7.11(a)
Accounting Firm	Section 2.5(d)	Insurance Cap	Section 7.11(b)
Accrued Bonus Amounts	Section 1.1	Insurance Policies	Section 4.18
Acquisition	Recitals	Investor Rights Agreement	Section 1.1
Adjusted Closing Date Statement	Section 2.5(b)	Labor Agreement	Section 4.6(a)(xiii)
Agreement	Preamble	Legal Restraints	Section 8.1(b)
Anti-Bribery Laws	Section 4.22(a)	Manufacture	Section 1.1
Approved 280G Gross-up Payments	Section 1.1	Material Contracts	Section 4.6(a)
Bankruptcy and Equity Exception	Section 3.2(a)	Milestone Company RSU Consideration	Section 2.2(b)
Benefit Plan	Section 4.12(a)	New Hire	Section 7.10(a)
Burdensome Condition	Section 7.2(b)	OFAC	Section 4.22(b)
Buyer	Preamble	Paris	Preamble
Closing	Section 2.4	Paris Company Shares	Recitals
Closing Company RSU Consideration	Section 2.2(b)	Pre-Closing Period	Section 6.1
Closing Date	Section 2.4	Preparation Period	Section 2.5(b)
Closing Payments	Section 2.2(a)(i)	Price Decrease	Section 2.5(e)
Closing Shares	Section 2.2(a)(i)	Price Increase	Section 2.5(e)
Combined Company/Rome Group Taxes	Section 7.7(b)	Privileged Deal Communications	Section 10.15(d)
Commerce	Section 4.22(b)	Release	Section 7.10(a)
Company	Preamble	Representatives	Section 7.2(d)
Company Benefit Plan	Section 4.12(a)	Resolution Agreement	Section 2.5(d)
Company Partner	Section 4.20(b)	Resolution Period	Section 2.5(d)
Company Permits	Section 4.17	Review Period	Section 2.5(c)
Company RSU Consideration	Section 2.2(b)	ROFR and Co-Sale Agreement	Section 1.1
Company Shares	Recitals	Rome	Preamble
Company Systems	Section 4.24(a)	Rome Company Shares	Recitals
Company/Rome Group	Section 7.7(b)	Rome Covered Person	Section 7.5
Confidentiality Agreement	Section 6.3(a)	Rome FDA Meeting	Section 7.1(f)
Continuing Employees	Section 7.1(f)	Rome Parties	Section 10.15(b)
Current Employee	Section 7.10(a)	Safety Notices	Section 4.20(g)
D&O Insurance	Section 7.11(b)	Sanctioned Country	Section 4.22(b)
Deal Communications	Section 10.15(d)	Sanctioned Person	Section 4.22(b)
Dispute Notice	Section 2.5(c)	Sanctions Authorities	Section 4.22(b)
Disputed Amount	Section 2.5(c)	Sellers	Preamble
Effective Date	Preamble	Selling Releasees	Section 7.9(b)
Encumber	Section 1.1	Sensitive Business Information	Section 6.3(b)
End Date	Section 9.1(b)	Severance Obligations	Section 7.10(a)
Equity Commitment Letter	Section 1.1	Specified Transaction Expenses	Section 1.1
Estimated Closing Cash	Section 2.5(a)	State Department	Section 4.22(b)
Estimated Closing Date Statement	Section 2.5(a)	Tax Contests	Section 7.7(a)
Estimated Closing Indebtedness	Section 2.5(a)	Terminated Employee	Section 7.10(a)
Estimated Net Working Capital Adjustment Amount	Section 2.5(a)	Termination Fee	Section 9.3(a)
Estimated Transaction Expenses	Section 2.5(a)	Termination Fee Forfeiture	Section 9.3(a)
Financial Statements	Section 4.7	Termination Fee Request	Section 9.3(a)
Freshfields	Section 10.15(a)	Trade Controls	Section 4.22(b)
GAAP	Section 4.7	Transfer Taxes	Section 7.7(g)
Healthcare Data Requirements	Section 4.21(a)	Transferred Releasees	Section 7.9(a)

ARTICLE II.

SALE AND PURCHASE OF COMPANY SHARES

2.1 Sale and Purchase. Upon the terms and subject to the conditions set forth herein, at the Closing:

(a) Rome shall sell, assign, transfer, convey and deliver to the Buyer (or, subject to Section 10.4(d), an Affiliate of the Buyer designated by the Buyer), free and clear of any and all Encumbrances (other than transfer restrictions under applicable securities Laws), and the Buyer shall purchase and acquire from Rome, the Rome Company Shares; and

(b) Paris shall sell, assign, transfer, convey and deliver to the Buyer (or, subject to Section 10.4(d), an Affiliate of the Buyer designated by the Buyer), free and clear of any and all Encumbrances (other than transfer restrictions under applicable securities Laws), and the Buyer shall purchase and acquire from Paris, the Paris Company Shares.

2.2 Payment of Purchase Price; Treatment of Company RSUs.

(a) In consideration for the transfer of the Company Shares as set forth in Section 2.1, at the Closing the Buyer shall:

(i) pay or cause to be paid to each Seller an amount in cash (without interest) equal to the product of (A) the Per Share Value and (B) the sum of (without duplication) (1) the aggregate number of shares of Common Stock held by such Seller as of immediately prior to the Closing plus (2) the aggregate number of shares of Common Stock issuable to such Seller upon conversion of any shares of Preferred Stock held by such Seller, in each case as of immediately prior to the Closing (the result of such sum, a Seller's "Closing Shares"), which payment shall be made by wire transfer of immediately available funds to the accounts designated by the applicable Seller in writing for such payment (the "Closing Payments"); and

(ii) pay, on behalf of the Company Group, by wire transfer of immediately available funds to accounts set forth on the Estimated Closing Date Statement, the aggregate amount of the Specified Transaction Expenses (if any) that is due and payable from the Company Group at the Closing and for which invoices have been received from the payees thereof (it being understood that Rome shall request the payees of Specified Transaction Expenses to deliver invoices therefor at least two Business Days prior to the Closing).

(b) Immediately prior to, and contingent on, the Closing but no later than the termination of employment of the Company Group Employees pursuant to Section 7.10(a), each unvested Company RSU that is outstanding and held by a Company Group Employee shall become fully vested. At the Closing, without any further action on the part of the Buyer, the Company, the Sellers or any Company RSU Holder, each Company RSU that is outstanding (whether vested or unvested) as of immediately prior to the Closing (taking into account the vesting pursuant to the immediately preceding sentence) shall be canceled and converted into the right to receive an amount in cash (without interest) equal to (i) the product of (A) the Per Share Value and (B) the aggregate number of shares of Common Stock issuable pursuant to such Company RSU (the aggregate amounts payable to the Company RSU Holders pursuant to this Section 2.2(b)(i), the "Closing Company RSU Consideration") and (ii) when, as and if the Milestone Payment described in Exhibit G becomes payable pursuant to the terms of this Agreement, an amount in cash (without interest) equal to the product of (1) the Per Share Milestone Payment and (2) the aggregate number of shares of Common Stock issuable pursuant to such Company RSU (the "Milestone Company RSU Consideration" and the aggregate amounts payable to the Company RSU Holders pursuant to this Section 2.2(b), the "Company RSU Consideration"), less any applicable withholding taxes. Prior to the Closing, the Company's board of directors (or, if appropriate, any committee thereof) will take all action reasonably necessary to effectuate the treatment of the Company RSUs set forth in this Section 2.2(b) and the Company shall have taken all actions necessary such that the Company Stock Plan shall be terminated effective as of the Closing in accordance with its terms. No less than ten days prior to the Closing Date, the Company shall deliver to the Buyer a revised version of Section 4.3(c)(i) of the Company Disclosure Schedule.

(c) At the Closing, the Buyer shall pay or cause to be paid to the Company an amount in cash (without interest) equal to the sum of the aggregate Closing Company RSU Consideration payable to the Company RSU Holders and the employer portion of any employment or payroll Taxes related thereto. Subject to the receipt of such amounts from the Buyer, the Company shall pay the applicable Closing Company RSU Consideration, subject to Section 2.3, to the applicable Company RSU Holders no later than the next first applicable regularly scheduled payroll date following the Closing Date.

2.3 Tax Withholding. The Buyer and any other applicable withholding agent shall be entitled to deduct and withhold from the Purchase Price, or other payment otherwise payable pursuant to this Agreement, the amounts required to be deducted and withheld under the Code, or any applicable provision of any federal, state, local or non-U.S. Law; provided that, other than with respect to (a) any deduction or withholding in respect of failure by a Seller to deliver the certificate described in Section 2.6(c), (b) any backup withholding and (c) amounts treated as compensation, the Buyer shall use commercially reasonable efforts to (i) provide the Sellers with reasonable advance notice of any proposed withholding and (ii) cooperate with the Sellers in good faith prior to withholding any amounts payable to the Sellers in order for Sellers to provide any documentation or information available to reduce or eliminate such withholding. Any amounts so withheld shall be timely paid over to the appropriate Tax Authority. To the extent that amounts are so deducted or withheld and paid over to the appropriate Tax Authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the applicable Person in respect of whom such deduction and withholding was made.

2.4 Closing. The closing of the Acquisition (the "Closing") shall take place at 10:00 a.m. (Eastern Time) on the tenth day after the satisfaction or waiver (to the extent permitted by applicable Law) of the conditions set forth in Article VIII (other than those conditions that by their terms are to be satisfied at the Closing, but subject to the satisfaction or waiver (to the extent permitted by applicable Law) of those conditions at such time), or at such other time and date as the Buyer and Rome may agree in writing; provided that if the waiting period under the HSR Act referred to in Section 8.1(a)(i) is terminated prior to the end of the initial waiting period as a result of a grant of a request for early termination or otherwise, then the condition set forth in Section 8.1(a)(i) shall not be deemed to have been satisfied until such time as the waiting period under the HSR Act would have expired had such request for early termination not been granted. The Closing shall take place remotely via the electronic exchange of documents and signature pages or at such location as Rome and the Buyer agree. The date on which the Closing occurs is herein referred to as the "Closing Date."

2.5 Actions in Connection with Closing.

(a) No less than five Business Days prior to the Closing Date, the Company shall deliver to the Buyer a statement (the "Estimated Closing Date Statement"), substantially in the form attached hereto as Exhibit D, setting forth in reasonable detail the Company's good faith estimation of (a) the Closing Indebtedness (the "Estimated Closing Indebtedness") and the components thereof, (b) the Closing Net Working Capital, the Net Working Capital Adjustment Amount (the "Estimated Net Working Capital Adjustment Amount") and the components thereof, (c) Closing Cash (the "Estimated Closing Cash") and the components thereof and (d) the Transaction Expenses (the "Estimated Transaction Expenses"), in each case of the foregoing clauses (a) through (d), calculated in accordance with the definitions hereof and, if applicable, the Accounting Principles, together with reasonably detailed supporting documentation used to calculate the foregoing amounts. At least seven Business Days prior to the Closing, the Company shall deliver to the Buyer a preliminary Estimated Closing Date Statement for information purposes only (which shall not be considered the Estimated Closing Date Statement for any purpose hereunder). The Buyer shall be entitled, no later than six Business Days prior to the Closing Date, to comment on and request reasonable changes to the preliminary Estimated Closing Date Statement, and the Company shall consider in good faith any changes the Buyer proposes to the preliminary Estimated Closing Date Statement within such time period; provided that (i) the Buyer shall not have any right to delay or prevent the Closing or the payment of the Estimated Purchase Price as a result of any disagreement with the Company's estimates set forth in the preliminary or actual Estimated Closing Date Statement and (ii) the Company shall not be required to accept any comment made by the Buyer and shall be entitled to determine the contents of the Estimated Closing Date Statement in its sole discretion. The Company shall, no later than five Business Days prior to the Closing Date, provide the Buyer in writing with the calculation of the Per Share Value based on the Estimated Closing Date Statement, the Pro Rata Portion of each Seller, the aggregate Closing Payment payable to each Seller at the Closing.

(b) Within 90 days after the Closing Date, the Buyer shall prepare and deliver to Rome, on behalf of the Sellers, a statement (the "Adjusted Closing Date Statement"), substantially in the form of Exhibit D hereto, setting forth the Buyer's determination of (1) the Closing Indebtedness and the components thereof, (2) the Closing Net Working Capital, the Net Working Capital Adjustment Amount and the components thereof, (3) Closing Cash and the components thereof, (4) the Transaction Expenses and (5) the Purchase Price calculated based on the foregoing, in each case, calculated in accordance with the definitions hereof and, if applicable, the Accounting Principles, together with reasonably detailed supporting documentation used to calculate the foregoing amounts. During such 90-day period, Rome shall afford to the Buyer's Representatives reasonable access, upon reasonable notice, during normal business hours and in a manner that does not disrupt or interfere with Rome's business operations, to all of the properties, books, Contracts, personnel and records of Rome as the Buyer shall reasonably request in connection with the preparation of the Adjusted Closing Date Statement, in each case solely to the extent relating to the Company Group or Program Business and in Rome's possession and subject to the execution by the Buyer of customary access letters in respect of external accountants and auditors. If the Buyer fails to deliver the Adjusted Closing Date Statement within such 90 day period following the Closing Date, then Rome, on behalf of the Sellers, shall have the right to either (i) determine that the calculations of the amounts in the Estimated Closing Date Statement will be deemed to be the amounts set forth in the Adjusted Closing Date Statement, the Purchase Price will be deemed to be the Estimated Purchase Price, and the Price Increase and the Price Decrease will be deemed to be zero, and such amounts shall be final and binding upon the Parties for all purposes of this Agreement and not subject to appeal, or (ii) Rome, on behalf of the Sellers, will have the right, within 30 days thereafter (the "Preparation Period"), to prepare and deliver to the Buyer the Adjusted Closing Date Statement (it being understood that, if Rome exercises such right to prepare and deliver the Adjusted Closing Date Statement, the provisions in paragraph (c) below shall be construed in a manner such that the Buyer has the right to review such statement and submit a Dispute Notice thereto). During the Preparation Period (if applicable), the Review Period and the Resolution Period, the Buyer shall afford to Rome's Representatives reasonable access, upon reasonable notice, during normal business hours and in a manner that does not disrupt or interfere with the Buyer's business operations, to all of the properties, books, Contracts, personnel and records of the Company Group as Rome shall reasonably request, and, during such period, the Buyer shall furnish promptly to Rome the information concerning the business, properties, assets and personnel of the Company Group as Rome may reasonably request as reasonable to make such review and examination in connection with the delivery of the Adjusted Closing Date Statement, subject in each case to the execution by Rome of customary access letters in respect of external accountants and auditors.

(c) Rome, on behalf of the Sellers, shall have 30 days following receipt of the Adjusted Closing Date Statement to review such statement (the "Review Period"). If Rome disagrees with the Adjusted Closing Date Statement, Rome, on behalf of the Sellers, shall notify the Buyer in writing of such disagreement during the Review Period, which notice (a "Dispute Notice") shall describe in reasonable detail the nature of such disagreement, including the specific items involved and the dollar amounts thereof (each, a "Disputed Amount"), together with reasonably detailed documentation supporting Rome's position with respect to the Disputed Amounts. If Rome does not deliver a Dispute Notice within the Review Period, the Adjusted Closing Date Statement, as delivered pursuant to Section 2.5(b) above, shall be considered final, binding and non-appealable upon the Parties. If Rome delivers a Dispute Notice within the Review Period, then (i) the Disputed Amounts shall be resolved pursuant to Section 2.5(d) and (ii) such portions of the Adjusted Closing Date Statement that are not Disputed Amounts shall be considered final, binding and non-appealable upon the Parties.

(d) During the 30 days immediately following the delivery of a Dispute Notice (the "Resolution Period"), Rome, on behalf of the Sellers, and the Buyer shall seek in good faith to resolve any differences that they may have with respect to the matters identified in the Dispute Notice (and all discussions related thereto shall, unless otherwise agreed to by the Buyer and Rome, be governed by Rule 408 of the Federal Rules of Evidence (and any applicable similar state rules)). If the Buyer and Rome are unable to resolve all Disputed Amounts within the Resolution Period, then the Disputed Amounts shall be referred for final determination to Deloitte & Touche LLP, or if Deloitte & Touche LLP is unwilling or unable to serve, then an independent nationally recognized accounting firm of independent certified public accountants, jointly determined by the Buyer and Rome (such firm, or another firm determined pursuant to this Section 2.5(d), the "Accounting Firm"), within 15 days after the end of such 30-day period. The Accounting Firm shall act as expert, and not as arbitrator, and shall consider only those Disputed Amounts which the Buyer and Rome have been unable to resolve during the Resolution Period. Neither Rome nor the Buyer (and none of their respective Representatives) shall have any *ex parte* communications (whether written or oral) or meetings with the Accounting Firm without the prior written consent of the other party. The Accounting Firm shall deliver to the Buyer and Rome, as promptly as practicable, and in any event within 30 days after its appointment, a written report setting forth the resolution of such Disputed Amounts. The Accounting Firm determination shall be based solely on presentations and supporting material provided by Rome and the Buyer and not pursuant to any independent review, and based solely on the definitions of Closing Indebtedness, Closing Net Working Capital, Closing Cash and Transaction Expenses contained herein and the Accounting Principles. The Accounting Firm shall only be permitted to determine an amount with respect to any Disputed Amount that is either the amount of such Disputed Amount as proposed by the applicable Party in the Adjusted Closing Date Statement or the Dispute Notice or an amount in between the two amounts. Such report shall be final, binding and non-appealable upon the Parties, absent fraud or manifest error. Upon the decision of the Accounting Firm, the Adjusted Closing Date Statement, as adjusted to the extent necessary to reflect the Accounting Firm's decision, shall be final, binding and non-appealable upon the Parties. At any time, the Buyer and Rome may agree to settle any remaining Disputed Amount, including any such Disputed Amount submitted to the Accounting Firm, which agreement shall be in writing and shall be deemed final, binding and non-appealable upon the Parties with respect to the subject matter of such Disputed Amount so resolved (the "Resolution Agreement"); provided that, if the Accounting Firm has been engaged, the Buyer and Rome shall promptly provide a copy of such Resolution Agreement to the Accounting Firm and instruct the Accounting Firm not to resolve such Disputed Amount so resolved, it being agreed that if the Accounting Firm nonetheless resolved such Disputed Amount for any reason, the Resolution Agreement shall control. The fees, costs and expenses of the Accounting Firm shall be allocated between the Buyer and Rome based upon the percentage that the portion of the contested amount not awarded to each such party bears to the amount actually contested by such party. For example, if Rome claims the aggregate Purchase Price is $1,000 greater than the amount determined by the Buyer, and if the Accounting Firm ultimately resolves the dispute by awarding the Sellers $300 of the $1,000 contested, then the costs and expenses of arbitration shall be allocated 30% (i.e., 300 ÷ 1,000) to the Buyer and 70% (i.e., $700 ÷ 1,000) to Rome. The dispute resolution provisions set forth in this Section 2.5 shall be the sole and exclusive remedy of the Parties for any disputes related to the Closing Indebtedness and the components thereof, the Closing Net Working Capital, the Net Working Capital Adjustment Amount and the components thereof, the Closing Cash and the components thereof, and the Transaction Expenses; provided that the foregoing shall not prohibit any Party from instituting an Action to enforce any final determination of the Purchase Price by the Accounting Firm pursuant to the terms and conditions of this Section 2.5(d).

(e) In the event that the amount of the Purchase Price as finally determined pursuant to this Section 2.5 is greater than the Estimated Purchase Price (the "Price Increase"), the Buyer shall pay to each Seller, by wire transfer of immediately available funds, an amount in cash equal to such Seller's Pro Rata Portion of the Price Increase. In the event that the Purchase Price as finally determined pursuant to this Section 2.5 is less than the Estimated Purchase Price (the "Price Decrease"), each Seller shall pay to the Buyer, by wire transfer of immediately available funds, an amount in cash equal to its Pro Rata Portion of the Price Decrease.

(f) Any amounts payable pursuant to Section 2.5(e) shall be paid within five Business Days after final determination of the Purchase Price by wire transfer of immediately available funds to an account designated by the Party receiving such payment within two Business Days after such final determination.

(g) Any payment made pursuant to this Section 2.5 or Section 2.7 shall be treated as an adjustment to the Purchase Price for federal, state, local and non-U.S. income Tax purposes, except as and to the extent required to be treated as interest under applicable Law, including Sections 483 and/or 1274 of the Code.

2.6 Closing Deliverables.

(a) At the Closing, (i) each of Rome and Paris shall deliver to the Buyer an instrument of assignment transferring all of their right, title and interest to the Rome Company Shares and the Paris Company Shares, respectively, to the Buyer and (ii) the Company shall record the transfer of the Company Shares in its books and records and the Buyer as the record holder of the Company Shares.

(b) At or prior to the Closing, Rome shall deliver or cause to be delivered to the Buyer an executed counterpart of the Joinder Agreement, duly executed by or on behalf of Paris.

(c) At or prior to the Closing, (i) the Company shall deliver to the Buyer a certificate and notice to the Internal Revenue Service from the Company, dated as of the Closing, in a form and substance prescribed by the Treasury Regulations promulgated under Sections 897 and 1445(b)(2) of the Code stating that the Company is not, and has not been during the relevant period specified in Section 897(c)(1)(ii) of the Code, a "United States real property holding corporation" within the meaning of Section 897(c) of the Code, in substantially the form attached hereto as Exhibit E, and (ii) each of Rome and Paris shall deliver to the Buyer an IRS Form W-9 or Form W-8BEN-E, as applicable.

(d) At or prior to the Closing, (i). Rome shall deliver or cause to be delivered to the Buyer an executed counterpart of the Trademark Assignment Agreement and (ii). the Company shall deliver to the Buyer an executed counterpart of the Trademark Assignment Agreement.

2.7 Milestone Payments.

(a) After the Closing, if applicable, the Buyer shall pay or cause to be paid the Milestone Payment owing pursuant to Exhibit G, such payment obligation (if any) to be governed by the terms and conditions of Exhibit G and this Article II. Any such right is solely a contractual right and is not a security for purposes of any federal or state securities Laws. In the event that the Buyer becomes obligated pursuant to the terms of Exhibit G to make the Milestone Payment, when, as and if such Milestone Payment becomes payable pursuant to the terms of this Agreement, the Buyer shall pay or cause to be paid no later than the time provided for in Exhibit G:

(i) to each Seller an amount in cash (without interest) equal to the product of (A) the Per Share Milestone Payment Amount and (B) such Seller's Closing Shares, which payment shall be made by wire transfer of immediately available funds to the account designated by the applicable Seller in writing for such payment; and

(ii) to the Company an amount in cash (without interest) equal to the sum of the aggregate Milestone Company RSU Consideration payable to the Company RSU Holders and the employer portion of any employment or payroll Taxes related thereto. Subject to the receipt of such amounts from the Buyer, the Company shall pay the applicable Milestone Company RSU Consideration, subject to Section 2.3, to the applicable Company RSU Holders, not later than five (5) days following the date of receipt of the Milestone Company RSU Consideration.

(b) The right of any Seller or Company RSU Holder to receive the portion of the Milestone Payment payable thereto shall not be evidenced by any form of certificate or instrument, and does not represent any ownership or equity interest in any member of the Company Group, Buyer or any of their respective Affiliates and does not entitle any such entitled Person to any voting rights or any rights to dividend payments. The right of the Sellers and the Company RSU Holders to receive the portion of the Milestone Payment payable thereto shall not be assignable or transferable except, (i) in the case of any Company RSU Holder, (A) by will or the laws of intestacy, (B) by operation of law, (C) by gift without consideration of any kind to a spouse, lineal descendant, sibling, parent, heir, executor, administrator, testamentary, trustee, legatee or beneficiary of such Company RSU Holder or (D) to a trust that is for the exclusive benefit of such Company RSU Holder or its permitted transferees under clause (C) above and (ii) in the case of a Seller, to an Affiliate of such Seller; provided, that in each case, written notice of such assignment and transfer shall be promptly delivered to the Buyer by the transferor or assignor, which notice shall expressly set forth the transferor or assignor and the transferee or assignment, the rights to which such transfer or assignment related and the effective date of such transfer; provided further, that as a condition to such transfer or assignment, the parties to such transfer or assignment shall agree to provide to the Buyer any additional evidence of the transfer or assignment that the Buyer may reasonably request. None of the Buyer or any member of the Company Group or any of their respective Affiliates shall give effect to any purported assignment or transfer made in contravention of this Section 2.7.

ARTICLE III.
SELLER REPRESENTATIONS AND WARRANTIES

Except (a) as set forth in the Company Disclosure Schedule and (b) for the representations and warranties set forth in Section 3.4, which are made solely by Rome, each Seller, severally but not jointly, represents and warrants to the Buyer as follows (and, for clarity, each Seller shall make the representations below solely as to itself):

3.1 Organization, Standing and Power . Such Seller is a legal entity duly organized, validly existing and in good standing (to the extent good standing is a legal principle applicable in such jurisdiction) under the Laws of the jurisdiction of its formation and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now being conducted and as contemplated to be conducted immediately after the Closing, except as would not reasonably be expected to have a material impact on the Company Group, taken as a whole.

3.2 Authority; Required Filings and Consents; No Conflict.

(a) Such Seller has all requisite legal capacity, right, corporate power and authority to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated hereby in accordance with the terms of this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary company action on the part of such Seller, and no other action on the part of such Seller is necessary to authorize the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated by this Agreement. This Agreement has been duly executed and delivered by such Seller and, assuming due authorization, execution and delivery by the Buyer, constitutes a valid and binding obligation of such Seller, enforceable against such Seller in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar Laws of general applicability relating to or affecting creditors' rights and to general equity principles (the "Bankruptcy and Equity Exception"). No vote or other approval of the equityholders of such Seller is required in connection with the execution, delivery or performance of this Agreement or to consummate the transactions contemplated by this Agreement in accordance with the terms hereof, whether by reason of applicable Law, the Constitutive Documents of such Seller, the rules or requirements of any securities exchange, or otherwise.

(b) No notices to, consents or approvals of, waivers, permits or authorizations from or filings or registrations with, any Governmental Authority are required at or prior to the Closing by such Seller in connection with the execution, delivery or performance by such Seller of this Agreement or to consummate the transactions contemplated hereby, except for (i) as required under the HSR Act, the Securities Act or the Exchange Act and (ii) any such notice, consent, approval, waiver, permit, authorization, filing or registration, the failure to make or obtain would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect.

(c) Subject to the making of the notices, filings and registrations and receipt of the consents, approvals, waivers, permits and authorizations referred to in Section 3.2(b), and the expiration of related waiting periods, the execution, delivery and performance of this Agreement by such Seller and the consummation of the transactions contemplated hereby do not and shall not (i) conflict with, result in a breach or violation of, or a default under, any (A) applicable Law, (B) applicable Order, (C) applicable Governmental Authorization or (D) Contract to which such Seller is a party, or give rise to any right of termination, cancellation or acceleration under such Contract, except, in each case of the foregoing clauses (A) through (D), as would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect or a Business Material Adverse Effect, or (ii) conflict with, or result in a breach or violation of, or a default under, the Constitutive Documents of such Seller.

3.3 Ownership of the Company Shares. Paris is the sole holder of record and sole beneficial owner of the Paris Company Shares and Rome is the sole holder of record and sole beneficial owner of the Rome Company Shares. Paris, with respect to the Paris Company Shares, and Rome, with respect to the Rome Company Shares, has good and valid title to such Company Shares. Such Company Shares shall be, as of the Closing, free and clear of all Encumbrances (other than transfer restrictions under applicable securities Laws). The applicable Company Shares are the only Capital Stock in the Company owned by such Seller. Such Seller has full right, power and authority to sell, transfer, assign and deliver the relevant Company Shares to the Buyer as provided in this Agreement, and, at the Closing, such Seller shall convey to the Buyer good, valid and marketable title to the relevant Company Shares, free and clear of any and all Encumbrances (other than transfer restrictions under applicable securities Laws). Other than the Paris Transaction Agreements, there are no outstanding options, purchase rights, rights of first refusal, warrants, calls, puts, convertible securities or other contractual obligations pursuant to which any Seller has, directly or indirectly, granted any option, warrant or other right to any Person to acquire any of the Company Shares to be sold by such Seller.

3.4 Litigation. There are, and since January 1, 2020, there have been no Actions pending or, to the Knowledge of Rome, threatened in writing against Rome and, to the Knowledge of Rome, there is no basis for an Action against Rome, at law or in equity, by or before any Governmental Authority or by any Third Party as of the date hereof, except as would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect. The representations and warranties in this Section 3.4 shall not apply to any Action commenced or threatened on or after the Effective Date arising in relation to this Agreement or the Acquisition under any Antitrust Law.

3.5 No Additional Representations or Warranties. Except as expressly set forth in Article III, Article IV or the certificate delivered pursuant to Section 8.2(c), as applicable, none of the Sellers, their Affiliates or any of their Representatives makes or has made any other representation or warranty, express or implied, at law or in equity, in respect of either Seller, the Company Group, any of their respective Affiliates, any Program Compound, any Program Product or the Program Business. Any such other representation or warranty is hereby expressly disclaimed. In particular, without limiting the foregoing disclaimer, except for the representations and warranties expressly made by each Seller in Article III, by Rome in Article IV or in the certificate delivered pursuant to Section 8.2(c), as applicable, none of the Sellers, their Affiliates or any of their Representatives makes or has made any representation or warranty to the Buyer or any of its Affiliates or Representatives with respect to (a) any financial projection, forecast, estimate or budget of future results or future financial condition relating to the Company Group, any Program Compound, any Program Product or the Program Business, or (b) any oral or written information presented to the Buyer or any of its Affiliates or Representatives in the course of their due diligence investigation of the Company Group, any Program Compound, any Program Product or the Program Business, the negotiation of this Agreement or in the course of the Acquisition.

3.6 No Reliance. Except for the express representations and warranties contained in Article V and the certificate delivered pursuant to Section 8.3(c), each Seller (a) acknowledges and agrees that none of the Buyer, nor any of its Affiliates, nor any other Person, made or shall be deemed to have made any representation or warranty to either Seller or any of their Affiliates, express or implied, at Law or in equity, on behalf of the Buyer or any of its Affiliates and (b) hereby disclaims reliance on any and all statements, representations or warranties with respect to the Buyer except those expressly set forth in Article V or the certificate delivered pursuant to Section 8.3(c), and acknowledges and agrees there are no, and it is not relying upon any, representations or warranties of any kind (express, implied, as to merchantability or fitness for a particular purpose or otherwise) except as expressly set forth in Article V or the certificate delivered pursuant to Section 8.3(c). Any claims a Seller may have for breach of representation or warranty shall be based solely on the representations and warranties of the Buyer expressly set forth in Article V and the certificate delivered pursuant to Section 8.3(c).

ARTICLE IV.
ROME REPRESENTATIONS AND WARRANTIES

Except as set forth in the Company Disclosure Schedule, Rome represents and warrants (i) with respect to the members of the Company Group and (ii) in connection with the Program Business as follows:

4.1 Organization, Standing and Power. The Company is a corporation duly incorporated, validly existing and in good standing under the Laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now being conducted. The Company and each other member of the Company Group is duly qualified to do business and, where applicable as a legal concept, is in good standing as a foreign corporation in each jurisdiction in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing as would not reasonably be expected to have, individually or in the aggregate, a Business Material Adverse Effect. The Company has made available to the Buyer a complete and correct copy of each of the members of the Company's Constitutive Documents, each as amended to the date hereof, and such documents are in full force and effect. The Company is in compliance with all of the terms and provisions of its Constitutive Documents in all material respects.

4.2 Subsidiaries. Section 4.2 of the Company Disclosure Schedule contains a true, correct and complete list, as of the Effective Date, of each Subsidiary of the Company, the jurisdiction of its incorporation or organization and the record owner of the outstanding Capital Stock of each such Subsidiary. All Capital Stock of each member of the Company Group or Subsidiary of the Company has been duly authorized, validly issued, fully paid and non-assessable (to the extent applicable as a legal concept) and, as of the Closing, will be owned by the Company free and clear of all Encumbrances (other than transfer restrictions under applicable securities Laws). There is no Capital Stock of any Subsidiary of the Company issued and outstanding that is not owned by the Company. The Company has made available to the Buyer true, complete and correct copies of the Constitutive Documents of each of the Company's Subsidiaries. The Company does not own, directly or indirectly, any Capital Stock in any Person other than its Subsidiaries.

4.3 Capitalization.

(a) Section 4.3(a) of the Company Disclosure Schedule sets forth a true and complete list, as of the Effective Date, of the authorized Capital Stock of the Company and the number of shares of Capital Stock issued and outstanding and the holders of record of such shares. The Company Shares constitute all of the issued and outstanding shares of Capital Stock of the Company.

(b) All Company Shares are duly authorized and validly issued, are fully paid and non-assessable and are free and clear of all Encumbrances (other than transfer restrictions under applicable securities Laws, restrictions under the Company's Constitutive Documents and the Paris Transaction Agreements and any Encumbrances that will be released at the Closing). There are no declared or accrued but unpaid dividends with respect to any shares of Capital Stock of the Company. The Company Shares have not been issued in violation of any applicable Laws or the Company's Constitutive Documents. The Company does not have any bonds, notes, debentures or other debt securities outstanding that have voting rights or are exercisable or convertible into, or exchangeable or redeemable for, or that give any Person a right to subscribe for or acquire, Capital Stock or any other Equity Securities of the Company. Other than pursuant to the Paris Transaction Agreements, there are no obligations, contingent or otherwise, to acquire, repurchase, redeem (or establish a sinking fund with respect to redemption) or otherwise acquire any shares of Capital Stock in the Company or for a member of the Company Group to make any investment (in the form of a loan, capital contribution or similar transaction) in any other Person. Except for the Company RSUs and the Company Shares, the Company does not have any other Equity Securities that are issued and outstanding.

(c) Section 4.3(c)(i) of the Company Disclosure Schedule sets forth a true and complete list, as of the Effective Date, of each outstanding Company RSU, including (i) the award holder, (ii) the number of shares of Common Stock issuable under such Company RSU, (iii) the grant date, (iv) vesting commencement date and (v) the vesting schedule (including any acceleration provisions). Section 4.3(c)(ii) of the Company Disclosure Schedule sets forth a true and complete list, as of the Effective Date, of each Person with an offer letter or other Contract that contemplates a grant of Company RSUs or other Equity Securities, which have not been granted or issued as of the date hereof.

4.4 Title to Properties and Assets; Sufficiency of Assets.

(a) The Company Group does not lease, sublease or own, and has never leased, subleased or owned, any real property.

(b) All of the tangible assets of the Company Group are in all material respects in reasonably serviceable operating condition and repair (giving due account to the age and length of use of same, ordinary wear and tear excepted), and are adequate in all material respects for the uses to which they are being put. The Company Group holds good, valid and enforceable title to each material asset which it purports to own or, in the case of leased assets or assets held under license, a good and valid leasehold or license interest in, each material asset used by the Company Group in connection with the Program Business, in each case, free and clear of any Encumbrances of any kind, other than Permitted Encumbrances, including Permitted Licenses.

(c) At the Closing, the Company Group will own or have the right to use (including by means of ownership or rights pursuant to licenses or other Contracts) all of the assets, properties and rights necessary to conduct the Program Business in substantially the same manner in all material respects as conducted as of the date of this Agreement and as of immediately prior to the Closing (other than any assets, properties or services provided pursuant to the Services Agreement); provided that the foregoing shall not constitute a representation or warranty regarding the infringement, misappropriation or other violation of any Intellectual Property of any Person, which is addressed exclusively in the first two sentences of Section 4.16(b). No member of the Company Group has any Liabilities other than Liabilities incurred in connection with the Company Group's efforts to Develop, Manufacture and Commercialize the Program Compounds and Program Products or otherwise in the conduct by the Company Group of the Program Business.

4.5 No Conflict. Subject to the making of the notices, filings and registrations and receipt of the consents, approvals, waivers, permits and authorizations referred to in Section 3.2(b) and the expiration of related waiting periods, the execution, delivery and performance of this Agreement by the Company and the consummation of the transactions contemplated hereby do not and shall not (a) conflict with, result in a breach or violation of, or a default under, or give rise to any Encumbrance (other than Permitted Encumbrances) or any acceleration of remedies, penalty, increase in benefit payable or right of termination, cancellation, suspension, revocation, amendment or cancellation under, or forfeiture of, as applicable, any (i) applicable material Law, (ii) applicable material Order, (iii) applicable material Governmental Authorization or (iv) material Contract to which the Company is a party or subject to or by which it or any of its assets or properties is otherwise bound, except in the foregoing clauses (i) through (iv), as would not (A) reasonably be expected to have, individually or in the aggregate, a Business Material Adverse Effect or (B) reasonably be expected to prevent or materially delay the ability of the Company to consummate the transactions contemplated by this Agreement, or (b) conflict with or result in a breach or violation of, or a default under, the Constitutive Documents of the Company.

4.6 Material Contracts.

(a) Section 4.6(a) of the Company Disclosure Schedule sets forth a true, correct and complete list of the following Contracts in effect, as of the Effective Date, to which the Company Group is party or by which it is bound (including, in each case, all amendments, extensions and supplements thereto as of the Effective Date) (the "Material Contracts") (it being understood, for the avoidance of doubt, that (i) this Section 4.6 shall not require the disclosure of, and Material Contracts shall not be deemed to include, any Contract which contains any of the provisions or obligations set forth below, but which provisions or obligations have terminated or expired in accordance with their terms and for which there is no continuing liability and (ii) the Material Contracts shall not be deemed to include [***], which are addressed exclusively by Section 4.6(c)):

(i) any Contract containing covenants requiring a member of the Company Group to indemnify or hold harmless any Person, other than indemnification provisions in contract manufacturing agreements, contract research agreements, clinical trial agreements, institutional review board/independent ethics committee agreements and other services agreements, material transfer agreements or Permitted Licenses, in each case, entered into in the Ordinary Course;

(ii) any Contract containing covenants requiring the Company Group not to (or that otherwise restrict or limit the Company Group's ability to) (A) compete or otherwise conduct activities in any line of business or geographical area (including any covenant not to compete with respect to, or that otherwise restricts, the Manufacture, marketing, distribution or sale of any product or product line) or (B) solicit any customer of any Person or solicit or hire any employee, consultant or independent contractor of any Person; provided that this clause (B) shall not apply to non-solicitation and no-hire provisions contained in non-disclosure agreements or Contracts with employees, consultants and other individual service providers entered into in the Ordinary Course;

(iii) any Contract that contains (A) exclusivity obligations (including providing for the grant of exclusive sales, distribution, marketing or other exclusive rights), (B) most favored nation obligations, (C) minimum purchase requirements or (D) other similar provisions, in each case that would apply to the activities of Buyer after the Closing with respect to the Program Business;

(iv) any Contract relating to (A) a joint venture, strategic alliance or partnership or (B) material research and development, pre-clinical or clinical trial or manufacturing services;

(v) any Contract (A) relating to any incurrence, assumption or guarantee of indebtedness for borrowed money in excess of $2,000,000, (B) relating to any interest rate, derivatives, currency exchange, commodities or hedging transactions or (C) granting any Person and Encumbrance on, mortgaging or pledging any material assets of any member of the Company Group, other than Permitted Encumbrances (including Permitted Licenses) or Encumbrances that will be released at or prior to Closing;

(vi) any Contract involving aggregate outstanding payment obligations by or to a Person with a value in excess of $2,000,000 in any consecutive 12-month period;

(vii) any Contract requiring the Development by a member of the Company Group of any compound or product;

(viii) any Contract relating to any acquisition or disposition of any business, (whether by merger, sale of equity, sale of assets or otherwise), assets (other than sales of inventory), properties or rights with a value in excess of $2,000,000;

(ix) any Contract relating to the settlement, conciliation or similar agreement with (A) any Governmental Authority that provides for payments of money by a member of the Company Group or (B) other Person that provides for payments in excess of $500,000, or that provides for any continuing material non-monetary obligations on the part of the Company Group or the Company Group Employees (or after the Closing, the Buyer and its Affiliates);

(x) any Contract containing any capital commitment on behalf of a member of the Company Group or otherwise requiring any member of the Company Group to make any capital expenditure in an amount in excess of $10,000,000;

(xi) any Contract involving the payment of royalties or other amounts calculated upon the revenues, profits or income of any member of the Company Group or the Program Business or income, profits or revenues related to any product of any member of the Company Group, Intellectual Property owned by or licensed to any member of the Company Group or the Program Business;

(xii) any Contract granting any Person any right of first refusal, right of first negotiation, option to purchase, option to license or any other similar preferential rights with respect to the equity, assets, products of any member of the Company Group, Intellectual Property owned by or licensed to any member of the Company Group or the Program Business;

(xiii) any collective bargaining agreement or other labor-related Contract with a union, works council, labor organization or other employee representative of the members of the Company Group (each, a "Labor Agreement");

(xiv) any Contract which imposes an obligation on any member of the Company Group with respect to an "earn out," royalty, milestone, contingent purchase price or similar contingent payment obligation;

(xv) any Contract directly with any Governmental Authority;

(xvi) any Contract (A) by which any member of the Company Group licenses or sublicenses to or otherwise authorizes any Third Party to use, or covenants not to sue or grants an immunity from suit with respect to, any Intellectual Property or (B) by which any member of the Company Group is granted a license or sublicense to, is authorized to use, or is granted a covenant not to sue or immunity from suit with respect to, any Intellectual Property, in each case other than (1) Contracts for any commercially available, off-the-shelf software products, (2) non-exclusive licenses or other rights granted to or by the Company Group pursuant to any fee-for-service agreements in connection with the provision of services to the Company Group entered into the Ordinary Course, or (3) agreements between the Company Group and its employees, independent contractors or consultants on the Company Group's standard forms thereof, which have been made available to the Buyer;

(xvii) any Contract that constitutes a Contract or agreement with any manager, officer, employee, director, stockholder or other Affiliate of any member of the Company Group (other than (A) Affiliate contracts that have been or will be terminated prior to the Closing without any continuing liability or obligation to any party and (B) Benefit Plans);

(xviii) any stockholders agreement, investors rights agreement, registration rights agreement or similar Contract not otherwise disclosed as a Paris Transaction Document or a Company's Constitutive Document; or

(xix) any Contract where a member of the Company Group is a lessee of leased real property.

(b) The Company has made available to the Buyer correct and complete copies of each Material Contract (or form thereof), subject to redactions for competitively sensitive information (which has been made available on an outside counsel basis). (i) Each Material Contract is in full force and effect, subject to the Bankruptcy and Equity Exceptions, (ii) all of the Material Contracts are valid, binding and enforceable against the relevant member of the Company Group and, to Rome's Knowledge, the other party(ies) thereto, in accordance with their terms except as enforcement may be limited by the Bankruptcy and Equity Exceptions, (iii) no member of the Company Group is in breach or default under any Material Contract to which it is party, (iv) to Rome's Knowledge, no other party is in breach or default under such Material Contracts and, to Rome's Knowledge, no event has occurred, and no condition or state of facts exists which, with the passage of time or the giving of notice or both, would constitute a material breach, default or termination under any Material Contract, (v) as of the Effective Date, no written notice of any claim of breach, violation, default or termination under a Material Contract has been received by any member of the Company Group, (vi) no member of the Company Group has waived any of its rights under any Material Contract to which it is party and (vii) no member of the Company Group has provided or received any written notice of any intention to terminate or cancel any Material Contract, in the case of each of clauses (i) through (vii), except as would not reasonably be expected to be, individually or in the aggregate, material to the Program Business, taken as a whole. For clarity, the foregoing representations and warranties in this Section 4.6(b) shall not apply with respect to [***].

(c) To Rome's Knowledge, the Company has made available to the Buyer a correct and complete copy of each of [***] as in effect on the Effective Date, subject to redactions for competitively sensitive information (which has been made available on an outside counsel basis). To Rome's Knowledge: (i) [***] is in full force and effect, subject to the Bankruptcy and Equity Exceptions, and is valid, binding and enforceable against the parties thereto, in accordance with its terms except as enforcement may be limited by the Bankruptcy and Equity Exceptions, (ii) as of the Effective Date, no party is in material breach or default under any [***] and no event has occurred, and no condition or state of facts exists which, with the passage of time or the giving of notice or both, would constitute a material breach, default or termination under any [***], (iii) as of the Effective Date, Paris has not received written notice of any claim of material breach, default or termination under a [***] and has not waived any of its material rights under any [***] and (iv) as of the Effective Date, Paris has not provided or received any written notice of any intention to terminate or cancel any [***].

4.7 Financial Statements. Section 4.7 of the Company Disclosure Schedule sets forth true, complete and correct copies of the unaudited balance sheet of the Company as of the Most Recent Balance Sheet Date and the unaudited statement of income of the Company for the six months ended as of such date (collectively, the "Financial Statements"). The Financial Statements (a) have been derived from the books and records of the Company Group, (b) have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") applied on a consistent basis throughout the periods covered and (c) present fairly in all material respects, the consolidated financial condition and results of operations of the Company Group as of the date thereof and for the period referred to therein (subject to the absence of footnotes and normal year-end close adjustments and certain stand-alone adjustments). Notwithstanding anything to the contrary in this Section 4.7, the Buyer acknowledges that, throughout the respective periods covered by the Financial Statements, the Company Group has not operated as a separate stand-alone entity but rather has operated as a unit with the Rome Group and as a result, the Buyer acknowledges that the Financial Statements include costs charged by the Rome Group for services provided to the Company Group, and do not include all the costs necessary to operate the Company Group on a stand-alone basis. To Rome's Knowledge, there has never been any fraud that involves any of the management or other employees of the Rome Group who have a role in the preparation of financial statements or the internal accounting controls used by the Company Group, any material claim or allegation regarding any of the foregoing.

4.8 Absence of Certain Changes.· Since the Most Recent Balance Sheet Date, (a) through the Effective Date, except in connection with the negotiation, preparation and execution of this Agreement, other agreements and arrangements prepared in connection herewith and the Acquisition or the process by which Rome or its Representatives solicited, discussed or negotiated strategic alternatives with respect to the Company Group or the Program Business, the Program Business has been conducted in the Ordinary Course in all material respects, (b) there has been no Business Material Adverse Effect that is continuing and (c) there has not been any action taken by the Company Group that would have required the Buyer's consent pursuant to Sections 6.2(g), 6.2(h), 6.2(j), 6.2(p) or (to the extent related to the foregoing) 6.2(y) had such action occurred after the date hereof and prior to the Closing.

4.9 Liabilities. The Company Group does not have any liabilities, except for (a) liabilities reflected or reserved for in the Financial Statements, (b) liabilities incurred or accrued in the Ordinary Course since the Most Recent Balance Sheet Date (none of which is a liability for violations of Law or breach of any such Contracts), (c) liabilities incurred pursuant to or in connection with this Agreement or the transactions contemplated hereby, (d) liabilities incurred in connection with obligations under Contracts of the Company Group (none of which is a liability for breach of any such Contracts), (e) liabilities incurred following the Effective Date in compliance with (and to the extent specifically addressed by) Section 6.2 or (f) other liabilities that would not, individually or in the aggregate, be material to the Company Group, taken as a whole. The Company Group is not party to any material off-balance sheet transactions or Contracts.

4.10 Taxes.

(a) Each member of the Company Group has timely filed all material Tax Returns that it was required to file, and all such Tax Returns were true, correct and complete in all material respects. Each member of the Company Group has paid on a timely basis all material Taxes due or payable by or with respect to it, whether or not shown on any Tax Return.

(b) No member of the Company Group is subject to nor has submitted an application for any letter rulings, technical advice memoranda, closing agreements or similar documents issued by a Tax Authority relating to Taxes.

(c) No examination or audit of any member of the Company Group by any Tax Authority in respect of material Taxes is currently in progress or, to Rome's Knowledge, threatened in writing, and no deficiencies for Taxes or other assessments relating to Taxes have been claimed, proposed or assessed in each case in writing against any member of the Company Group.

(d) No member of the Company Group has been informed in writing by any jurisdiction that the jurisdiction believes that any member of the Company Group was required to file any material Tax Return that was not filed or that any member of the Company Group is or may be subject to taxation in that jurisdiction in each case which has not been subsequently resolved.

(e) No member of the Company Group is the beneficiary of any extension of time within which to file any material Tax Return which extension is still in effect other than any such extension obtained in the Ordinary Course. No member of the Company Group has been granted any extension or waiver of the limitation period applicable to the collection or assessment of a material amount of Taxes which extension or waiver is still in effect.

(f) No member of the Company Group (i) has ever been a member of a group of corporations filing (or required to file) consolidated, combined or unitary Tax Returns, (ii) has any liability for Taxes of any Person other than a member of the Company Group under Treasury Regulations Section 1.1502-6 or any similar provision of state, local or non-U.S. Law or (iii) is a party to or bound by any Tax Sharing Agreement.

(g) There are no material Encumbrances with respect to Taxes upon any of the assets or properties of any member of the Company Group, other than Permitted Encumbrances.

(h) No member of the Company Group has distributed to its shareholders or security holders stock or securities of a controlled corporation, nor have stock or securities of any member of the Company Group been distributed, in a transaction to which Section 355 of the Code applies in the two years prior to the Effective Date.

(i) No member of the Company Group has engaged in a "listed transaction" as set forth in Treasury Regulations Section 1.6011-4(b)(2).

(j) All material Taxes required by Law to be withheld or collected by each member of the Company Group has been duly withheld or collected and, to the extent required, have been timely paid to the proper Governmental Authority.

(k) No member of the Company Group (i) has agreed, nor is it required, to make any adjustment under Section 481(a) of the Code by reason of a change in accounting method or otherwise that occurred prior to Closing, or (ii) has executed or entered into a closing agreement pursuant to Section 7121 of the Code or similar provision of Law.

(l) No member of the Company Group will be required to include a material amount of income in, or exclude a material item of deduction from, taxable income for any period (or portion thereof) ending after the Closing Date as a result of (i) a change in method of accounting made prior to the Closing, (ii) closing agreement, advance pricing agreement or other agreement with any Tax Authority relating to Taxes entered into prior to the Closing, (iii) an installment sale or open transaction disposition entered into on or prior to the Closing or (iv) a prepaid amount received prior to the Closing. No member of the Company Group has any liability for Taxes pursuant to Section 965 of the Code.

(m) No member of the Company Group has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(n) Each member of the Company Group has, to the extent applicable, (i) properly complied with all legal requirements to defer the amount of the employer's share of any "applicable employment taxes" under Section 2302 of the CARES Act (or any similar provision of state, local or non-U.S. Law), and (ii), properly complied with all legal requirements and duly accounted for any available Tax credits under Sections 7001 through 7005 of the Families First Act and Section 2301 of the CARES Act.

(o) No member of the Company Group (i) is or has been resident for Tax purposes in a country outside of its country of organization or incorporation; (ii) has, or has ever had, a permanent establishment or other taxable presence in any country other than its country of organization or incorporation; and (iii) is, or has ever been, subject to income Tax in a country outside its country of organization or incorporation.

4.11 Environmental Matters.

(a) Except as would not reasonably be expected to have a material impact on the Company Group, taken as a whole, (i) the Company Group and, with respect to the Program Business, the Rome Group are, and have been, in compliance with all Environmental Laws and (ii) the Rome Group has not received any communication (written or oral) from a Governmental Authority that alleges that the Company Group or, with respect to the Program Business, the Rome Group, is not in compliance with, or has liability under, any Environmental Laws.

(b) Except as would not reasonably be expected to have, individually or in the aggregate, a Business Material Adverse Effect, there is no Environmental Claim pending or, to Rome's Knowledge, threatened against the Company Group, the Program Business or against any Person whose liability for any Environmental Claim the Company or the Program Business has retained, assumed, undertaken or otherwise become subject to, either contractually or by operation of Law.

(c) Except as would not reasonably be expected to have, individually or in the aggregate, a Business Material Adverse Effect, there are no past or present actions, activities, circumstances, conditions, events or incidents, including the release, emission, discharge, presence, generation, manufacture, treatment, storage, transport, distribution, marketing, sale, disposal or arrangement for disposal of, exposure of any Person to, or ownership or operation of any property or facility contaminated by, any Materials of Environmental Concern, in each case that would reasonably be expected to (i) form the basis of any Environmental Claim against the Company Group, the Program Business or against any Person whose liability for any Environmental Claim the Company Group has retained, assumed, undertaken or otherwise become subject to, either contractually or by operation of Law, or (ii) otherwise result in any costs or liabilities under Environmental Law.

4.12 Employee Matters.

(a) Section 4.12(a) of the Company Disclosure Schedule sets forth a correct and complete list, as of the Effective Date, of each material Benefit Plan, and separately designates (i) each Benefit Plan that is sponsored by a professional employer organization and (ii) each Benefit Plan that is sponsored, maintained or contributed to (or required to be contributed to) by any member of the Company Group or with respect to which any member of the Company Group has any current, future or contingent liability (a "Company Benefit Plan"), none of which is an International Plan. A "Benefit Plan" is each "employee benefit plan" (as such term is defined in Section 3(3) of ERISA), whether or not subject to ERISA, and any employment, individual consulting, bonus, retention, change in control, deferred compensation, incentive compensation, commission, equity purchase, option, warrant, restricted equity, equity appreciation, phantom equity or other equity or equity-related, severance or termination pay, hospitalization, medical, life, disability, supplemental unemployment benefits, paid time off, leave, profit-sharing, pension, retirement plan, program, policy, agreement or arrangement, or other benefit or compensation plan, program, policy, agreement (including but not limited to employment agreements) or arrangement, whether written or unwritten in each case that is (i) maintained, sponsored, entered into, contributed to or required to be contributed to by the Rome Group for the benefit of any current or former Company Group Service Provider with respect to or in consideration for such Company Group Service Provider's services provided to the Company Group or (ii) with respect to which the Company Group has or may have any direct or indirect liability or obligation.

(b) With respect to each material Benefit Plan, the Company has made available to the Buyer complete and correct copies of the plan documents, including any amendments thereto, all related trust, or other funding documents, insurance contract and any other material related agreement, and in the case of unwritten material Benefit Plans, written descriptions thereof, in each case, if applicable.

(c) No Benefit Plan is and no member of the Rome Group or any ERISA Affiliate maintains, sponsors or contributes to (or is required to contribute to) or has ever maintained, sponsored, contributed to or been required to contribute to, and does not otherwise have any current or contingent liability or obligation under or with respect to, (i) a "defined benefit plan" as defined in Section 3(35) of ERISA or any other plan that is or was subject to Section 302 or Title IV of ERISA or Section 412 of the Code, (ii) a "multiemployer plan" within the meaning of Section 3(37) of ERISA, (iii) a "multiple employer plan" within the meaning of Section 210 of ERISA or Section 413(c) of the Code, (iv) a "multiple employer welfare arrangement" within the meaning of Section 3(40) of ERISA or (v) post-retirement or post-termination health or life insurance or other similar benefits (other than health continuation coverage required by Part 6 of Subtitle B of Title I of ERISA, Section 4980B of the Code for which the covered Person pays the full cost of coverage). No member of the Company Group has any material current or contingent liability or obligation as a consequence of at any time being considered a single employer under Section 414 of the Code with any other Person.

(d) Except for the Severance Obligations, the Company RSU Consideration and the Approved 280G Gross-up Payments, neither the execution and delivery of this Agreement nor the Acquisition (either alone or in combination with any other event), directly or indirectly, could (i) result in any payment becoming due to any current or former Company Group Service Provider, (ii) increase any payments or benefits under any Benefit Plan or otherwise payable to any current or former Company Group Service Provider or (iii) result in the acceleration of the time of payment, vesting or funding of any such benefit, or the forgiveness of any loan, under any Benefit Plan or otherwise with respect to any current or former Company Group Service Provider.

(e) Neither the execution and delivery of this Agreement nor the transactions contemplated herein (either alone or in combination with any other event) could give rise to any payment or benefit that could be an "excess parachute payment" as defined in Section 280G of the Code to any current or former Company Group Service Provider.

4.13 Compliance With Laws. Except as would not, individually or in the aggregate, be material to the Program Business, taken as a whole, (a) the Company Group has conducted the Program Business in compliance with all applicable Laws and Data Requirements and (b) no member of the Rome Group has received any written notice to the effect that the Program Business or any member of the Company Group is not in compliance with or has violated any such applicable Laws, Data Requirements, Orders or permits.

4.14 Legal Proceedings. Except as would not, individually or in the aggregate, be material to the Program Business, taken as a whole, and would not be reasonably expected to prevent or materially delay the ability of Rome or the Company to consummate the transactions contemplated by this Agreement, there is no, and since January 1, 2020, there has not been any, Action pending or, to Rome's Knowledge, threatened against the Rome Group that relates to the operation of the Program Business. Except as would not, individually or in the aggregate, be material to the Program Business, taken as a whole, or would not be reasonably expected to prevent or materially delay the ability of the Sellers or the Company to consummate the transactions contemplated by this Agreement, there are no Orders outstanding, or to Rome's Knowledge, threatened against the Company Group or, to Rome's Knowledge, the Sellers or with respect to the operation of the Program Business. There is no Action pending by the Rome Group, or, as of the Effective Date, which the Rome Group intends to initiate, against any other Person relating to either the Company Group or the Program Business. Except as would not, individually or in the aggregate, be material to the Program Business, taken as a whole, to Rome's Knowledge, there are no audits or investigations pending or threatened against the Company Group or with respect to the operation of the Program Business. The representations and warranties in this Section 4.14 shall not apply to any Action commenced or threatened or any Order that comes into effect, in each case, on or after the Effective Date arising in relation to this Agreement or the Acquisition.

4.15 Labor Matters.

(a) Section 4.15(a) of the Company Disclosure Schedule sets forth a correct and complete list, as of the Effective Date, of each Company Group Service Provider, specifying which Company Group Service Providers are employed or engaged by a member of the Company Group and which Company Group Service Providers are employed or engaged by Rome or one of its Affiliates other than the Company Group and for each specifying the (i) name or employee ID, (ii) job title, (iii) primary work location, (iv) date of hire and (v) hourly wage or base salary (as applicable) payable by the Company Group.

(b) No member of the Company Group is a party to or bound by any Labor Agreement, and no Company Group Employee is represented by any labor union, labor organization, works council, employee representative or group of employees with respect to their employment.

(c) No member of the Company Group is currently negotiating in connection with entering into, a collective bargaining agreement and, to Rome's Knowledge, there has not been any organizational campaign, petition or other unionization activity seeking recognition of a collective bargaining unit relating to any Company Group Service Provider. The consent or consultation of, or the rendering of formal advice by, any labor or trade union, works council or other employee representative body is not required for the Sellers to enter into this Agreement or to consummate any of the transactions contemplated hereby.

4.16 Intellectual Property.

(a) Section 4.16(a) of the Company Disclosure Schedule sets forth a true, complete and accurate list, as of the Effective Date, of all (i) (A) Patents issued by or filed with any Governmental Authority, (B) applied for or registered Trademarks, (C) applications for registration or registered Copyrights, and (D) internet domain name registrations, websites and social media handles, in each case, owned or licensed by any member of the Company Group, and (ii) Telavant Trademarks, in each case of clauses (i) and (ii), specifying as to each such item, as applicable, (w) the owner(s) of the item, (x) the jurisdictions in which the item is issued or registered or in which any application for issuance or registration has been filed, (y) the respective issuance, registration and application number of the item and (z) the date of application and issuance or registration of the item.

(b) To Rome's Knowledge, the Development, Manufacturing and Commercialization of any Program Compound and Program Product, and the operation of the Program Business, each as currently conducted or contemplated by any member of the Company Group to be conducted, does not infringe, misappropriate or otherwise violate, and has not infringed, misappropriated or otherwise violated, any valid Intellectual Property of any Person. No member of the Rome Group has filed, or threatened in writing to file, any Actions alleging that any Third Party has infringed, misappropriated or otherwise violated any Company Intellectual Property, and, to Rome's Knowledge, no Third Party infringes, misappropriates or otherwise violates, or has infringed, misappropriated, or otherwise violated, any Company Intellectual Property. No Third Party has filed, or threatened in writing to file, any Actions alleging that any member of the Rome Group has infringed, misappropriated or otherwise violated any Person's Intellectual Property rights (to the extent relating to the Program Business), and no such Actions are currently pending.

(c) All right, title and interest in and to all of the Company Intellectual Property is owned solely by a member of the Company Group (or, to Rome's Knowledge, solely or jointly by the Company Group's licensor or such licensor's licensor), free and clear of all Encumbrances (except for Permitted Encumbrances, including Permitted Licenses) and, with respect to each item of Company Owned Intellectual Property and, to Rome's Knowledge, Company Licensed Intellectual Property, (i) such Intellectual Property is not the subject of any reexamination proceeding or any other proceeding or dispute challenging its scope, enforceability or validity, (ii) no such item of Intellectual Property has been adjudged invalid or unenforceable, in whole or in part, (iii) no written notice from any Third Party challenging such Intellectual Property's validity, enforceability or ownership has been received by any member of the Rome Group, (iv) no opposition, extension of time to oppose, interference, rejection or refusal to register has been filed in connection with any application to register any such item of Intellectual Property, (v) except with respect to Patents, such Intellectual Property is subsisting, valid and enforceable and, with respect to Patents, is subsisting and, to Rome's Knowledge, valid and enforceable and (vi) the ownership of the entire right, title and interest in and to such Intellectual Property is recorded with the applicable Governmental Authority solely in the name of a member of the Company Group (or, to Rome's Knowledge, solely or jointly in the name of the Company Group's licensor or such licensor's licensor) or a member of the Company Group (or, to Rome's Knowledge, the Company Group's licensor or such licensor's licensor) is the applicant of record with respect thereto. To Rome's Knowledge, all fees, Taxes, annuities and other payments associated with filing, prosecuting, issuing, recording, registering or maintaining any Registered Company Intellectual Property have been paid in full in a timely manner to, and all documents and certificates related to such items have been filed with, the proper Governmental Authority. All current and former officers (or equivalents) and employees of the Rome Group who have conceived of or reduced to practice any Intellectual Property for or on behalf of any member of the Company Group (or otherwise relating to the Program Business) have executed and delivered to the Rome Group an agreement (containing no exceptions or exclusions from the scope of its coverage) regarding the protection of proprietary information and providing for the assignment to a member of the Company Group of any Intellectual Property made in the course of services performed by such officer (or equivalent) or employee for the Rome Group by such individuals, the current form of which has been made available to the Buyer. All current and former consultants and independent contractors of the Rome Group who have conceived of or reduced to practice any Intellectual Property relating to the Program Business for or on behalf of the Rome Group have executed and delivered to the Rome Group an agreement in substantially the form provided to the Buyer (containing no exceptions or exclusions from the scope of its coverage) regarding the protection of proprietary information and the assignment to a member of the Company Group of any Intellectual Property made by such consultant or independent contractor in the course of services performed for the Rome Group by such individuals relating to the Program Business. To Rome's Knowledge, no current or former officer (or equivalent), employee, consultant or independent contractor of the Rome Group is in violation of any term of any such proprietary information protection agreement or assignment agreement. The Company Group has complied in all material respects with all applicable procedures (y) mandated by applicable Law relating to assignments by employees or equivalents thereof with respect to Intellectual Property owned or purported to be owned by the Company Group or (z) that are reasonably necessary to effectuate the transfer of all right, title and interest in and to Intellectual Property owned or purported to be owned by any member of the Company Group to such member of the Company Group.

(d) With respect to each Patent included in the Registered Company Intellectual Property, (i) each member of the Company Group and, to Rome's Knowledge, any licensor to any member of the Company Group with respect to any such Patent, has complied in all material respects with all applicable Laws in connection with the filing and prosecution of such Patent, including the duty of candor to the U.S. Patent and Trademark Office and (ii) all listed inventors of such Patent (A) to Rome's Knowledge, are the sole inventors of such Patent and (B) have irrevocably assigned all right, title and interest in and to such inventions and Patent to a member of the Company Group (including through Third Parties, if applicable) (or, if such Patent is licensed to any member of the Company Group, to the licensor) pursuant to a valid and enforceable assignment agreement recorded with the applicable Governmental Authority.

(e) To Rome's Knowledge, none of the trade secrets or other material confidential or proprietary information of any member of the Company Group have been disclosed to any Person unless such disclosure was made pursuant to a commercially reasonable written agreement requiring such Person to maintain the confidentiality of such information. To Rome's Knowledge, there has not been any breach by any such Person of any such agreement. The Company Group has taken commercially reasonable measures at least commensurate with industry standards to maintain the confidentiality of all Company Intellectual Property, the value of which to the Company Group is contingent upon maintaining the confidentiality thereof, including any such trade secrets and other material confidential or other proprietary information.

(f) Except for any fees payable to a Governmental Authority to issue, register or maintain any of the Registered Company Intellectual Property and any payments required pursuant to a Contract listed in Section 4.6(a)(xvi) of the Company Disclosure Schedule, no payment of any kind is required to be made to any Person (including directors, officers, employees, consultants, contractors and agents of any member of the Rome Group) for the ownership or use of, or a covenant not to sue or immunity from suit under, any Company Intellectual Property. To Rome's Knowledge, no funding, facilities or personnel of any educational institution or Governmental Authority were used, directly or indirectly, to develop or create, in whole or in part, any Company Intellectual Property, any Program Compound or any Program Product.

(g) All Intellectual Property that is used or held for use by any member of the Company Group in connection with any Program Compound or Program Product or any Development, Manufacture or Commercialization thereof (including, for the avoidance of doubt, all such Intellectual Property licensed to Telavant under the Paris License Agreement) is included in the Company Intellectual Property; provided that the foregoing shall not constitute a representation or warranty regarding the infringement, misappropriation or other violation of any Intellectual Property of any Person, which is addressed exclusively in the first two sentences of Section 4.16(b).

(h) The Company Group's right, title or interest in, to or under any Company Intellectual Property as of immediately prior to the Closing will not be altered, encumbered, impaired or extinguished as a result of the consummation of the transactions contemplated by this Agreement at the Closing.

(i) No member of the Rome Group (other than the Company Group) or any of their respective Affiliates owns, licenses or otherwise has any right, title or interest (including any option or right to license) in, to or under any Company Intellectual Property, including any Intellectual Property, that is: (i) related to any Program Compound or Program Product or any Development, Manufacturing or Commercialization thereof, or (ii) otherwise necessary for any Development, Manufacture or Commercialization thereof. No member of the Rome Group or any of their respective Affiliates has transferred to any Third Party or other member of the Rome Group (other than the Company Group) ownership of any Intellectual Property that is: (x) related to any Program Compound or Program Product or any Development, Manufacturing or Commercialization thereof or (y) otherwise necessary for any Development, Manufacture or Commercialization thereof. No member of the Rome Group or any of their respective Affiliates has, and, to Rome's Knowledge, Paris has not, granted to any Person any license or other right with respect to any Company Intellectual Property related to a Program Compound or Program Product except under any Permitted License with respect thereto, the Paris License Agreement or the Trademark Assignment Agreement.

4.17 Governmental Authorizations. Except as would not reasonably be expected to be, individually or in the aggregate, material to the Program Business, taken as a whole, the Company Group has all Governmental Authorizations necessary to the conduct of the Program Business (the "Company Permits"), all of which are, and since January 1, 2020 have been, in full force and effect. The Company Group is, and since January 1, 2020 has been, in material compliance with the terms of the Company Permits, and, to Rome's Knowledge, no event has occurred which (a) allows, or as a result of which after notice or lapse of time would allow, revocation or termination thereof, (b) materially and adversely affects the rights of any member of the Company Group or (c) results in any other material impairment of the rights of the holder of any such Company Permit. No notice of cancellation, or of material default concerning any such Company Permit, has been received by any member of the Company Group and, to the extent related to the Program Business, any other member of the Rome Group, since January 1, 2020.

4.18 Insurance. Section 4.18 of the Company Disclosure Schedule sets forth a true and complete list, as of the Effective Date, of all insurance maintained by or on behalf of (a) the Company Group or (b) with respect to the Program Business, the Rome Group (delineating between clauses (a) and (b)) (the "Insurance Policies"). Such Insurance Policies are in full force and effect with respect to the applicable member of the Rome Group, and, to Rome's Knowledge, with respect to each other party thereto. All premiums due and payable under the Insurance Policies have been timely paid, and the Rome Group has complied in all material respects with the provisions of each Insurance Policy under which it is the insured party. There are no outstanding claims under the Insurance Policies which are reasonably likely to exhaust the applicable limit of liability. As of the Effective Date, no member of the Company Group or Rome has received any written notice from any insurer under any Insurance Policy terminating, canceling, revoking or amending any such policy.

4.19 Product Liability. Except as would not reasonably be expected to be, individually or in the aggregate, material to the Program Business, taken as a whole, no product liability claims have been received in writing by the Rome Group with respect to the Program Business or the Program Products and, to Rome's Knowledge, no such claims have been threatened against the Company Group or, to the extent relating to the Program Business or any of the Program Products, the Rome Group. Except as would not reasonably be expected to be, individually or in the aggregate, material to the Program Business, taken as a whole, there have been no notices received from a Governmental Authority and there is no Order outstanding against the Rome Group, in each case, relating to product liability claims relating to the Program Business or the Program Products.

4.20 Regulatory Matters.

(a) No member of the Rome Group has received any written communications from any Regulatory Authority, including regulatory or warning letters, FDA Form 483 observations, notices of adverse findings, Section 305 notices and similar letters or notices, alleging violations of applicable Laws (including applicable Healthcare Laws), in each case relating to any Program Product or Program Compound. The Rome Group is neither subject to, nor has received written notice of, any criminal, injunctive, seizure or civil penalty actions begun or, to Rome's Knowledge, threatened by any Regulatory Authority against the Rome Group, in each case relating to any Program Product or Program Compound.

(b) There are no (and the Rome Group with respect to the Program Business has not been notified by a Company Partner of any) pending, or to Rome's Knowledge, threatened regulatory actions against any member of the Rome Group with respect to the Program Business or, to Rome's Knowledge, any Person that Manufactures or Develops any Program Compound or Program Product pursuant to a Development, contract research, Manufacturing, supply or other collaboration arrangement with any member of the Rome Group with respect to the Program Business (each, a "Company Partner") by any Regulatory Authority (i) indicating that any of the Regulatory Filings are not in good standing with the relevant Regulatory Authority or (ii) alleging material non-compliance with any applicable Laws. The Rome Group has not, and, to Rome's Knowledge, no Company Partner has, committed any material violation of the rules and regulations of any Regulatory Authority which has not been cured by the applicable member of the Rome Group or, to Rome's Knowledge, any such Company Partner, or waived by the relevant Regulatory Authority, in each case relating to a Program Compound, Program Product or the Program Business.

(c) All Program Compounds and Program Products are being and have been Developed, Manufactured, distributed, used, processed, packaged, labeled, stored and tested by, or, to Rome's Knowledge, on behalf of, the Rome Group or the Company Group, in compliance in all material respects with all applicable requirements under all applicable Laws, including applicable Healthcare Laws. All preclinical studies and Clinical Trials conducted by, or, to Rome's Knowledge, on behalf of, the Rome Group with respect to the Program Products and Program Compounds are being and have been conducted in compliance in all material respects with the required experimental protocols, procedures and controls, GLP, GCP and GMP, as and to the extent applicable, and all applicable Laws (including applicable Healthcare Laws), and all applicable written instructions from institutional review boards and ethics committees. There exist no facts or circumstances that, to Rome's Knowledge, would warrant the issuance by the FDA or any other Regulatory Authority of a clinical hold on the investigation of any Program Compound or Program Product. None of the FDA, EMA or any other Regulatory Authority has, with respect to any Program Compound, Program Product or the Program Business, sent any written notices or other correspondence to the Rome Group with respect to any ongoing preclinical studies and Clinical Trials requiring the termination, suspension or material modification of such preclinical studies and Clinical Trials.

(d) Neither the Company Group nor, to Rome's Knowledge, any of their personnel, agents or subcontractors with respect to the Program Business has been convicted of any crime or engaged in any conduct which would reasonably be expected to result in debarment or disqualification by any Regulatory Authority, and there are no Actions pending or, to Rome's Knowledge, threatened in writing that would reasonably be expected to result in any such criminal liability or debarment or disqualification by any Regulatory Authority.

(e) The Rome Group has not imported, exported, marketed, sold, offered for sale or distributed for sale any Program Compounds or Program Products. Rome has made available to the Buyer complete and accurate copies of all documents provided to Rome by Paris in connection with the execution of the Paris Transaction Agreements as set forth in Section 4.4 of Schedule 4 of the Paris License Agreement and all material data and information with respect to the Program Compounds, Program Products and Program Business, including any material correspondence and minutes of meetings with Regulatory Authorities with respect thereto, received or generated following the execution of the Paris Transaction Agreements and prior to the execution of this Agreement (and will furnish to Buyer any such documents, data or information received or generated following the execution of this Agreement). To Rome's Knowledge, Paris has complied in all material respects with all of its obligations under Schedule 4 of the Paris License Agreement. All reports, applications, notifications, submissions, registrations, information, claims, filings, reports and statistics and other data (i) required by the FDA, EMA or any other Regulatory Authority to be maintained by or on behalf of the Rome Group in connection with, or (ii) that have otherwise been utilized by the Rome Group as the basis for, or submitted in connection with, any regulatory or marketing approvals or permits from the FDA, EMA or any other Regulatory Authority, in each case relating to the Program Products and Program Compounds, have been so maintained and were true, complete and correct in all material respects as of the date of submission (or were corrected in or supplemented by a subsequent filing or submission so as to be true, complete and correct in all material respects as of the date of such correction or supplementation), as applicable, and any necessary or required updates, changes, corrections or modification to such applications, submissions, information and data have been submitted to the FDA, EMA or other Regulatory Authority.

(f) The Rome Group has not received notice from any Company Partner of any material interruption of supply or Manufacturing capacity, shortage of raw materials, components or other Manufacturing problems that would have a material effect on the subsequent Development (as such Development is contemplated as of the Effective Date) of the Program Products or Program Compounds.

(g) Section 4.20(g) of the Company Disclosure Schedule sets forth a list, as of the Effective Date, of (i) all recalls, field notifications, investigator notices, safety alerts, IND safety reports or other notices of action relating to an alleged lack of safety of any Program Compound or Program Product issued by any member of the Rome Group ("Safety Notices"), (ii) the dates such Safety Notices, if any, were resolved or closed and (iii) any material complaints with respect to any Program Compound or Program Product that, to Rome's Knowledge, are currently unresolved.

(h) No member of the Company Group is a party to any corporate integrity agreement, monitoring agreement, consent decree, settlement order, deferred prosecution agreement or similar agreement with or imposed by any Governmental Authority arising from violations or alleged violations of Healthcare Laws and concerning any Program Products or Program Compounds, and no such agreement is currently pending, or, to Rome's Knowledge, threatened.

(i) No member of the Company Group intentionally (i) has made any materially untrue or fraudulent statement to any Regulatory Authority, (ii) has failed to disclose a material fact required to be disclosed to a Regulatory Authority or (iii) has committed any act or failed to commit any act that establishes the basis for any Regulatory Authority to invoke a material violation of applicable Law, in each case with respect to a Program Product, Program Compound or the Program Business.

4.21 Healthcare Data Privacy and Data Protection.

(a) The Rome Group has operated the Program Business in compliance in all material respects with all applicable Laws (including Healthcare Laws) and Contracts relating to Protected Health Information, medical records and medical information privacy that regulate or limit the maintenance, use, disclosure or transmission of medical records, identifiable patient information or other Personal Data made available to or collected by the Rome Group in connection with the operation of the Program Business as currently conducted (the "Healthcare Data Requirements"). The Rome Group has in all material respects implemented all confidentiality, security and other protective measures required by the Healthcare Data Requirements and applicable to the Program Business or the Company Group.

(b) The Rome Group is currently in compliance in all material respects and has at all times complied in all material respects with all Healthcare Data Requirements and Data Requirements with respect to the operation of the Program Business, including:

(i) requirements relating to the registration or notification of the access, collection, use, processing, storage, sharing, distribution, transfer, disclosure, security, destruction or disposal of Personal Data under Healthcare Data Requirements or Data Requirements;

(ii) requirements relating to requests from data subjects with respect to Personal Data held or controlled by the Rome Group under Healthcare Data Requirements or Data Requirements;

(iii) obligations set out in the Healthcare Data Requirements or Data Requirements;

(iv) requirements relating to the access, collection, use, processing, storage, sharing, distribution, transfer, disclosure, security, destruction or disposal of Personal Data by a data processor on the Rome Group's behalf under Healthcare Data Requirements or Data Requirements; and

(v) obtaining necessary consents from, and providing adequate privacy notice to, data subjects with respect to its processing of Personal Data relating to the Program Business.

(c) To Rome's Knowledge, no material breach has occurred with respect to any unsecured Protected Health Information, as that term is defined in 45 C.F.R. §160.103, maintained by or for the Rome Group with respect to the Program Business that is subject to the notification requirements of 45 C.F.R. Part 164, Subpart D or would require notification under any comparable Laws.

(d) To the extent required by the Healthcare Data Requirements or Data Requirements, the Rome Group has in place agreements with Third Parties processing Personal Data on its behalf in respect of the processing of data (if applicable) in connection with the Program Business which comply in all material respects with the Healthcare Data Requirements and Data Requirements.

(e) All Protected Health Information (including any sensitive Personal Data) accessed, collected, used, processed or stored by the Rome Group (or a Third Party engaged thereby) in connection with the Program Business or transferred to any Third Parties by the Rome Group in the operation of the Program Business has in all material respects been lawfully obtained, used, processed or transferred in accordance with (i) applicable Laws (including Healthcare Data Requirements), (ii) the requirements of Contracts to which the Rome Group is a party and (iii) published privacy policies of the Rome Group relating to its processing of Protected Health Information in connection with the Program Business that the Rome Group has communicated to Persons about whom such Personal Data relates.

(f) No member of the Rome Group is party to any pending, and no member of the Rome Group has received any written notices of any threatened, Action by any Third Party, or any inquiries or investigations by any Governmental Authority, or been the subject of any material claims or complaints to any regulatory or Governmental Authority, in each case in relation to its compliance with Healthcare Data Requirements or Data Requirements with respect to its operation of the Program Business. Except as would not, individually or in the aggregate, reasonably be expected to be material to the Company Group or the Program Business, taken as a whole, the completion of the Acquisition shall not violate any Healthcare Data Requirements or Data Requirements.

(g) Except as would not, individually or in the aggregate, reasonably be expected to be material to the Company Group or the Program Business, taken as a whole, no Person has (with respect to the Program Business):

(i) alleged in writing to the Rome Group that the Rome Group has failed to comply with the provisions of any Healthcare Data Requirements or Data Requirements; or

(ii) been awarded compensation by, or taken action against the Rome Group for breach of any Healthcare Data Requirements or Data Requirements, including with respect to the Rome Group's use of Personal Data or Protected Health Information.

4.22 Unlawful Payments; International Trade Compliance.

(a) None of the Sellers, the Company Group, nor, to Rome's Knowledge, any of their respective directors (or equivalent), officers (or equivalent), employees or agents or other Persons acting on behalf of or in the name of such Person with authority to do so (including its agents, distributors, sales intermediaries and/or channel partners) has, in connection with the operation of the Program Business: (i) offered or used any corporate funds, directly or indirectly, for any unlawful contribution, gift, entertainment or other unlawful expense; (ii) offered or made a direct or indirect unlawful payment or conveyance of something of value to any U.S. or non-U.S. government official, employee or political candidate or established or maintained any unlawful or unrecorded funds or (iii) offered, received, authorized, promised, agreed to or given any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment or gift of money or anything of value to or from any Third Party, including any U.S. or non-U.S. government official or employee of any Governmental Authority, in each case in material violation of the U.S. Foreign Corrupt Practices Act of 1977, the UK Anti-Bribery Act of 2010 or any similar Laws relating to the prevention of bribery, corruption or money laundering, including those concerning unlawful payments or gifts in any jurisdiction (collectively, "Anti-Bribery Laws"). The Company Group (and the Rome Group with respect to the Program Business) has instituted and maintains policies and procedures designed to promote, and which are reasonably expected to continue to promote, compliance with Anti-Bribery Laws.

(b) None of the Sellers, the Company Group, nor, to Rome's Knowledge, any of their respective directors (or equivalent), officers (or equivalent) or agents or other Persons acting on behalf of or in the name of such Person with authority to do so, has been or is currently (i) designated on any restricted party list or otherwise the subject or target of any sanctions or export-related restrictions administered by any Governmental Authority of the (A) United States, including, but not limited to, the U.S. Office of Foreign Assets Control's ("OFAC") Specially Designated Nationals and Blocked Persons List, the U.S. Department of Commerce ("Commerce") Denied Persons List, the Commerce Entity List and the U.S. Department of State ("State Department") Debarred List; (B) the United Nations; (C) the European Union; or (D) the United Kingdom (collectively, "Sanctions Authorities"), (ii) in the aggregate, 50 percent or greater, directly or indirectly, owned or controlled, or otherwise acting on behalf of, any Person or Persons described in clause (i) (each, a "Sanctioned Person"), (iii) organized or resident in a country or territory targeted by a comprehensive embargo administered by one or more Sanctions Authorities (which countries and territories, as of the date hereof, include Cuba, Iran, North Korea, Syria, the Crimea region of Ukraine, the so-called Donetsk People's Republic of Ukraine, and the so-called Luhansk People's Republic of Ukraine) ("Sanctioned Country"), (iv) participating in any transaction, whether directly or indirectly, for or on behalf of a Sanctioned Person, or any Sanctioned Country in material violation of economic sanctions Laws, (v) exporting (including deemed exportation), re-exporting (including deemed re-exportation), or transferring, directly or indirectly, any good, software, technology or services in material violation of any applicable export, re-export, transfer or import control or economic or trade sanctions Laws, including those administered by OFAC, Commerce or the State Department, (vi) participating in any export, re-export or transaction in material violation of applicable export, re-export, transfer or import control, anti-boycott, or economic or trade sanctions Laws, including, without limitation, support for international terrorism and nuclear, chemical or biological weapons proliferation (collectively, "Trade Controls") or (vii) otherwise in material violation of any Trade Controls.

4.23 Affiliate Transactions. Except as expressly contemplated by this Agreement, as of the Closing, no member of the Rome Group (other than the Company Group) shall own, purport to own or control or have any right to any material property or right, tangible or intangible, that is necessary for the operation of the Program Business, as currently conducted or as contemplated to be conducted immediately after the Closing (other than any assets, properties or services provided pursuant to the Services Agreement).

4.24 IT, Cybersecurity, Data Privacy.

(a) The Rome Group has (i) purchased a sufficient number of license seats, and scope of rights, with respect to all material third-party software used by the Company Group in connection with the Program Business as currently conducted, and (ii) has complied in all material respects with the terms of the corresponding agreement. The Rome Group has taken commercially reasonable efforts (including maintaining business continuity and disaster recovery policies) in accordance with normal industry practice to maintain and protect the integrity, security and operation of the material computer software and algorithms (including source code), programs, hardware, networks, databases, systems, telecommunications equipment and websites used in connection with or relied upon by the Program Business (and all information transmitted thereby or stored therein) (the "Company Systems"). There have been no material unauthorized intrusions, security breaches, ransomware attacks, successful phishing attempts or other attacks or material disruptions of the Company Systems that required or resulted in notification to any Governmental Authority or other Third Parties under Data Protection Laws; and to Rome's Knowledge, the Company Systems do not contain any malware, "Trojan horses," viruses or other malicious code. The Company Group maintains commercially reasonable security, disaster recovery and business continuity plans, procedures and/or facilities.

(b) All Personal Data collected, used or maintained by the Rome Group in connection with the Program Business has been collected, maintained, used and transferred in compliance in all material respects with applicable Data Requirements. All written, publicly-posted privacy policies of the Rome Group have been and are designed and administered materially in accordance with applicable Data Protection Laws. Except as would not reasonably be expected to be, individually or in the aggregate, material to the Program Business, taken as a whole, no Person has claimed any compensation from, and no Governmental Authority has made any allegation against, the Rome Group, and the Rome Group has not received any written notice from a Governmental Authority, related to the loss of or unauthorized disclosure or transfer of Personal Data or violation of any Data Requirement (in each case relating to the Program Business).

4.25 Paris License Agreement. As of the Effective Date, the Company has not exercised the Option for the Bispecific Antibody (each, as defined in the Paris License Agreement) under the Paris License Agreement.

4.26 Brokers. No agent, broker, investment banker, financial advisor or other firm or Person is, or shall be, entitled to any broker's, finder's, financial advisor's or other similar fee or commission by any member of the Company Group and there are no claims for such fees against any member of the Company Group based on any arrangement or agreement made by or on behalf of any member of the Company Group or any Seller in connection with any of the transactions contemplated by this Agreement.

4.27 No Additional Representations and Warranties. Except as expressly set forth in Article III, this Article IV or the certificate delivered pursuant to Section 8.2(c), none of Rome, the Company, any of their Affiliates or any of their Representatives makes or has made any other representation or warranty, express or implied, at law or in equity, in respect of the Company Group, any of their respective Affiliates, any Program Compound, any Program Product or the Program Business. Any such other representation or warranty is hereby expressly disclaimed. In particular, without limiting the foregoing disclaimer, except for the representations and warranties expressly made by Rome in this Article IV and the certificate delivered pursuant to Section 8.2(c), none of Rome, the Company, any of their Affiliates or any of their Representatives makes or has made any representation or warranty to the Buyer or any of its Affiliates or Representatives with respect to (a) any financial projection, forecast, estimate or budget of future results or future financial condition relating to the Company Group, any Program Compound, any Program Product or the Program Business or (b) any oral or written information presented to the Buyer or any of its Affiliates or Representatives in the course of their due diligence investigation of the Company Group, any Program Compound, any Program Product or the Program Business, the negotiation of this Agreement or in the course of the Acquisition.

4.28 No Reliance. Except for the express representations and warranties contained in Article V and the certificate delivered pursuant to Section 8.3(c), the Company (a) acknowledges and agrees that none of the Buyer, nor any of its Affiliates, nor any other Person, made or shall be deemed to have made any representation or warranty to the Company or any of its Affiliates, express or implied, at Law or in equity, on behalf of the Buyer or any of its Affiliates and (b) hereby disclaims reliance on any and all statements, representations or warranties except those expressly set forth in Article V and the certificate delivered pursuant to Section 8.3(c), and acknowledges and agrees there are no, and it is not relying upon any, representations or warranties of any kind (express, implied, as to merchantability or fitness for a particular purpose or otherwise) except as expressly set forth in Article V and the certificate delivered pursuant to Section 8.3(c). Any claims the Company may have for breach of representation or warranty shall be based solely on the representations and warranties of the Buyer expressly set forth in Article V of this Agreement and the certificate delivered pursuant to Section 8.3(c).

ARTICLE V.
REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer represents and warrants to the Sellers and the Company as follows:

5.1 Organization, Standing and Power. The Buyer is a legal entity duly organized, validly existing and in good standing under the Laws of the jurisdiction of its formation and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now being conducted and as contemplated to be conducted immediately after the Closing, except as would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect. The Buyer is duly qualified to do business and, where applicable as a legal concept, is in good standing as a foreign corporation in each jurisdiction in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing as would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect.

5.2 Authority; Required Filings and Consents; No Conflict.

(a) The Buyer has all requisite corporate power and authority necessary, to authorize, execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated hereby in accordance with the terms of this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of the Buyer, and no other action on the part of the Buyer is necessary to authorize the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated by this Agreement. This Agreement has been duly executed and delivered by the Buyer and, assuming due authorization, execution and delivery by the Sellers and the Company, constitutes a valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, subject to the Bankruptcy and Equity Exception. No vote or other approval of the equityholders of the Buyer is required in connection with the execution, delivery or performance of this Agreement or to consummate the transactions contemplated by this Agreement in accordance with the terms hereof, whether by reason of applicable Law, the Constitutive Documents of the Buyer, the rules or requirements of any securities exchange, or otherwise.

(b) No notices to, consents or approvals of, waivers, permits or authorizations from or filings or registrations with any Governmental Authority are required at or prior to the Closing by the Buyer in connection with the execution, delivery or performance by the Buyer of this Agreement or to consummate the transactions contemplated hereby, except for (i) as required under the HSR Act and (ii) any such notice, consent, approval, waiver, permit, authorization, filing or registration, the failure to make or obtain would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect. Neither the Buyer nor any of its Affiliates is subject to any “prior approval” requirement or agreement with the FTC or DOJ that would be applicable to the transactions contemplated by this Agreement.

(c) Subject to the making of the notices, filings and registrations and receipt of the consents, approvals, waivers, permits and authorizations referred to in Section 5.2(b) and the expiration of related waiting periods, the execution, delivery and performance of this Agreement by the Buyer and the consummation of the transactions contemplated hereby does not and shall not (i) conflict with, result in a breach or violation of, or a default under, any (A) applicable Law, (B) applicable Order, (C) applicable Governmental Authorization or (D) Contract to which the Buyer is a party or subject to or by which it or any of its assets or properties is otherwise bound, except in each of the foregoing clauses (A) through (D), as would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect, or (ii) conflict with, or result in a breach or violation of, or a default under, the Constitutive Documents of the Buyer.

5.3 Legal Proceedings. (a) There is no Action pending or, to the knowledge of the Buyer, threatened, against the Buyer or any of its Affiliates, except as would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect, and (b) neither the Buyer nor any of its Affiliates is subject to any outstanding Order, except as would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect. The representations and warranties in this Section 5.3 shall not apply to any Action commenced or threatened or any Order that comes into effect, in each case, on or after the Effective Date arising in relation to this Agreement or the Acquisition.

5.4 Financial Capability. The Buyer shall have at the Closing available sufficient cash or other sources of immediately available funds to pay all amounts payable pursuant to Article II. The Buyer's obligations hereunder are not subject to any conditions regarding the Buyer's ability to obtain financing for the consummation of the transactions contemplated by this Agreement.

5.5 Brokers. Other than Citibank, N.A., no broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Buyer, and the Buyer shall pay any such broker's commissions.

5.6 Acquisition of Transferred Interests for Investment. The Buyer has such knowledge and experience in financial and business matters and is capable of evaluating the merits and risks of its purchase of the Company Shares. The Buyer confirms that the Company has made available to the Buyer and the Buyer's agents the opportunity to ask questions of the officers and management employees of the Company Group and the Sellers as well as access to the documents, information and records of the Company Group and to acquire additional information about the business and financial condition of the Company Group and the Program Business, and the Buyer confirms that it has made an independent investigation, analysis and evaluation of the Company Group and the Program Business and their properties, assets, business, financial condition, prospects, documents, information and records. The Buyer is acquiring the Company Shares for investment and not with a view toward, or for sale in connection with, any distribution thereof, nor with any present intention of distributing or selling the Company Shares. The Buyer acknowledges that the Company Shares have not been registered under the Securities Act or any state securities Laws and agrees that the Company Shares may not be sold, transferred, offered for sale, pledged, hypothecated or otherwise disposed of without registration under the Securities Act, except pursuant to an exemption from such registration available under the Securities Act, to the extent applicable.

5.7 No Additional Representations or Warranties. Except as expressly set forth in this Article V and the certificate delivered pursuant to Section 8.3(c), none of the Buyer, its Affiliates or any of its or their Representatives makes or has made any other representation or warranty, express or implied, at law or in equity, in respect of the Buyer or its Affiliates. Any such other representation or warranty is hereby expressly disclaimed.

5.8 No Reliance. Except for the express representations and warranties contained in Article III, Article IV or the certificate delivered pursuant to Section 8.2(c), as applicable, the Buyer (a) acknowledges and agrees that none of the Sellers, the Company, any of their respective Affiliates or any other Person, made or shall be deemed to have made any representation or warranty to the Buyer or any of its Affiliates, express or implied, at Law or in equity, on behalf of either Seller, the Company or any of their respective Affiliates and (b) hereby disclaims reliance on any and all statements, representations or warranties except those expressly set forth in Article III, Article IV or the certificate delivered pursuant to Section 8.2(c), as applicable, and acknowledges and agrees there are no, and it is not relying upon any, representations or warranties of any kind (express, implied, as to merchantability or fitness for a particular purpose or otherwise) except as expressly set forth in Article III, Article IV or the certificate delivered pursuant to Section 8.2(c), as applicable. Any claims the Buyer may have for breach of representation or warranty shall be based solely on the representations and warranties expressly set forth in Article III, Article IV and the certificates delivered pursuant to Section 8.2(c), as applicable.

ARTICLE VI.
CONDUCT OF BUSINESS

6.1 Conduct of the Business of the Company. From the date of this Agreement through the earlier of the Closing or the valid termination of this Agreement (the "Pre-Closing Period"), except (i) as otherwise expressly required or contemplated by this Agreement, (ii) as required by or to comply with applicable Law, (iii) as disclosed in Section 6.1 of the Company Disclosure Schedule, (iv) for actions taken (or not taken) in good faith in order to respond to COVID-19 or COVID-19 Measures after, to the extent reasonably practicable, prior consultation with Buyer or (v) as otherwise consented to in writing by the Buyer (which consent shall not be unreasonably withheld, conditioned or delayed), the Company shall, and shall cause the members of the Company Group to, use commercially reasonable efforts to:

(a) conduct the Program Business in the Ordinary Course;

(b) perform the Development activities set forth in the Development Plan in all material respects in accordance with such Development Plan;

(c) preserve and maintain good working relationships with suppliers, vendors, partners, licensors, licensees, distributors, regulatory authorities and other Persons having a material business relationship with the Company Group or the Program Business; and

(d) keep available the services of its directors, officers and employees who are important to the operation of the Program Business as presently conducted.

Notwithstanding the foregoing, no action by any member of the Company Group with respect to any matters specifically addressed by Section 6.2 shall be deemed to be a breach of this Section 6.1, which matters shall be governed exclusively by Section 6.2.

6.2 Certain Restrictions During the Pre-Closing Period. Without limiting the generality of Section 6.1, during the Pre-Closing Period, except (i) as otherwise required or expressly contemplated by this Agreement, (ii) as required by or to comply with applicable Law, (iii) as disclosed in Section 6.2 of the Company Disclosure Schedule or (iv) as otherwise consented to in writing by the Buyer (which consent shall not be unreasonably withheld, conditioned or delayed), (x) Rome shall cause the members of the Company Group not to, and (y) solely to the extent relating to the Program Business, Rome shall not, and shall cause each other member of the Rome Group not to, with respect to the Program Business:

(a) modify, amend or change the Constitutive Documents of any member of the Company Group;

(b) issue, grant, sell, Encumber, dispose of or transfer any Capital Stock or other Equity Securities in any member of the Company Group, other than grants of Company RSUs to Company Group Service Providers not to exceed an aggregate number of shares of Common Stock underlying such Company RSUs of [***] of the Fully Diluted Share Number; provided that no grants shall be made on or after the date that is 10 days prior to the Closing Date;

(c) form a Subsidiary of any member of the Company Group;

(d) split, combine, redeem, repurchase, reclassify or otherwise acquire any Equity Securities of any member of the Company Group, except for acquisitions, or deemed acquisitions, of Capital Stock or Company RSUs effected in connection with (1) required tax withholding in connection with the vesting or settlement of Company RSUs pursuant to the terms of the Company RSUs in effect as of the date of this Agreement, (2) forfeitures of Company RSUs or (3) repurchases of Capital Stock held by employees that are subject to a repurchase right in favor of the Rome Group or the Company Group upon termination of employment;

(e) declare, set aside or pay any non-cash dividend (or cash dividend if the record date therefor is prior to and the payment date therefor is following the Closing) on, or make any other distribution in kind in respect of, any Capital Stock of the Company;

(f) in the case of the Company Group, create, incur, guarantee or assume any indebtedness for borrowed money, or issue or sell, or amend, modify or change any term of, any debt securities or options, warrants, calls or other rights to acquire any debt securities of any member of the Company Group or make or guarantee any loans, advances or capital contributions to, or investments in, any Person other than the Company Group;

(g) sell, lease, sublease, license, abandon, mortgage, pledge or otherwise encumber or subject to any Encumbrance (other than a Permitted Encumbrance, including a Permitted License), or otherwise dispose of any material tangible property or material tangible assets other than the sale of inventory or obsolete equipment in the Ordinary Course;

(h) (i) sell, assign, license, grant any immunity under, transfer, abandon, waive rights with respect to, permit to expire or lapse, convey, lease or otherwise dispose of or subject to any Encumbrance (other than a Permitted Encumbrance, including a Permitted License), any Company Intellectual Property, except for the expiration of such Intellectual Property at the end of the applicable maximum statutory term or (ii) disclose any trade secrets or other confidential information of any member of the Company Group to any Person other than pursuant to a written confidentiality and non-disclosure agreement entered into in the Ordinary Course;

(i) [reserved]

(j) with respect to any member of the Company Group, acquire or agree to acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets of, or by purchasing all or a substantial portion of the Equity Securities of, or by any other manner, any business or any other Person or any division thereof, or (ii) any assets that are material, individually or in the aggregate, to the Company Group or the Program Business, other than in the Ordinary Course or to the extent consistent with the Development Plan; provided that this clause (j) shall not apply to capital expenditures, which are governed by Section 6.2(t);

(k) adopt a plan of merger, consolidation, restructuring, recapitalization or other reorganization with respect to any member of the Company Group;

(l) commence, participate or agree to commence or participate in any bankruptcy, voluntary liquidation, dissolution, winding up, examinership, insolvency or similar proceeding with respect to any member of the Company Group;

(m) enter into any Contract to which a member of the Company Group is a party (or any substantially related Contracts, taken together) that, if entered into prior to the date hereof, would be a Material Contract, or amend in a material respect, renew, voluntarily terminate or waive any material rights under any Material Contract, in each case, other than (x) in the Ordinary Course (provided that in no event shall the Company be permitted to enter into any Contract that would be a Material Contract under Sections 4.6(a)(ii), 4.6(a)(iii)(A), 4.6(a)(iii)(B), 4.6(a)(iv), 4.6(a)(vii), 4.6(a)(xii), 4.6(a)(xiii), 4.6(a)(xv) or 4.6(a)(xvii) or amend in a material respect the provisions of any such Material Contract referenced in such sections) or (y) to the extent expressly contemplated by the Development Plan (excluding, for the avoidance of doubt, any Contract of the type referred to in the proviso to the immediately preceding clause (x)); provided that this clause (m) (other than the first proviso hereof) shall not restrict any action that is specifically addressed by and permitted by any other clause of this Section 6.2;

(n) [reserved]

(o) except (i) as required pursuant to the terms of any Benefit Plan in effect as of the date of this Agreement or as permitted to be established or amended by the terms of this Agreement, (ii) for any action (x) for which the Rome Group (other than the Company Group) shall be solely liable and (y) which will not result in any additional Liability of Buyer or the Company Group with respect to Section 280G or Section 4999 of the Code (including in connection with any obligation to provide any gross-up or reimbursement of any Tax or related interest or penalties or the disallowance of a federal income tax deduction) or (iii) entering into any agreement with respect to granting of rights to the Approved 280G Gross-up Payments subject to Buyer's prior review and comment (which shall not be unreasonably withheld, conditioned or delayed), (A) terminate, materially modify, establish or enter into any Benefit Plan or any arrangement that would be a Benefit Plan if in effect on the date hereof (except as required by applicable Law), (B) increase the compensation or benefits provided to any current or former Company Group Service Provider or (C) take any action to accelerate the time of payment, funding or vesting of any compensation or benefits under any Benefit Plan or otherwise, in each case with respect to Company Group Service Providers;

(p) with respect to any member of the Company Group, (i) make any material changes in Tax accounting methods, principles, practices or policies, except for any changes required by applicable Law, (ii) make, change or revoke any material Tax election or change any Tax accounting period, (iii) enter into any closing agreement relating to any material Tax, (iv) surrender, settle, compromise or otherwise abandon any right to claim a material Tax refund, (v) consent to any waiver or extension of the statute of limitations applicable to any material Tax claim or assessment (other than waivers or extensions requested in the Ordinary Course by a Tax Authority) or (vi) apply for or request any Tax ruling;

(q) with respect to any member of the Company Group, adopt or change any of the accounting methods or practices (including any change in depreciation or amortization policies or rates or any change to practices that would impact the methodology for recognizing revenue) used by the Company Group or the Program Business, in each case, unless required by GAAP or applicable Law or otherwise applicable to all of the members of the Rome Group;

(r) offer, propose to settle, settle or compromise any Action, or enter into any consent decree or settlement agreement with any Governmental Authority, in each case, other than (A) a settlement or release that contemplates only the payment prior to the Closing Date of money without ongoing limits on the conduct or operations of any member of the Company Group (other than obligations of confidentiality and non-disparagement and other obligations that are merely incidental to a settlement or compromise for the payment of money) or (B) settlements or compromises of any Action in the Ordinary Course or where the amount paid in settlement or compromise (in excess of amounts covered by a third-party indemnity or insurance) does not exceed $1,000,000 individually or $2,000,000 in the aggregate (but not including any such settlement or compromise that would impose any ongoing limits on the conduct or operations of any member of the Company Group (other than obligations of confidentiality and non-disparagement and other obligations that are merely incidental to a settlement or compromise for the payment of money));

(s) with respect to any member of the Company Group, enter into a lease or sublease of real property (whether as a lessor, sublessor, lessee or sublessee) (other than any such lease or sublease that is one year or less in duration or includes payment obligations not in excess of $100,000 on an annual basis);

(t) with respect to any member of the Company Group, make or agree to make any capital expenditures in excess of $5,000,000, in the aggregate, other than to the extent consistent with the Development Plan or the Company's budget for capital expenditures set forth in Section 6.2(t) of the Company Disclosure Schedule; provided that this clause (t) shall not apply to any acquisitions governed by Section 6.2(j);

(u) with respect to any member of the Company Group, (i) modify, extend, terminate or enter into any Labor Agreement or (ii) recognize or certify any labor union, labor organization, works council or group of employees as the bargaining representative for any Company Group Employees;

(v) implement or announce any layoffs, furloughs, reductions in force, plant closings, reductions in compensation or other similar actions with respect to Company Group Employees that would trigger notice obligations under the WARN Act;

(w) with respect to any member of the Company Group, waive or release any noncompetition, nonsolicitation, nondisclosure or other restrictive covenant obligation of any current or former Company Group Service Provider other than in the Ordinary Course;

(x) transfer the employment of (i) a Company Group Employee from the Company Group to the Rome Group (other than the Company Group), or (ii) any employee of the Rome Group from the Rome Group to the Company Group; or

(y) authorize any of, or commit, resolve or agree, whether in writing or otherwise, to take any of, the actions prohibited in Sections 6.2(a) through 6.2(x).

Notwithstanding anything to the contrary contained in this Agreement, nothing contained in this Agreement (i) shall give Buyer, directly or indirectly, the right to control or direct the business or operations of the Company Group, or to extent relating to the Program Business, the Rome Group, prior to the Closing, including the Program Business, or (ii) shall prohibit or otherwise in any way restrict any of the operations of the business of the Rome Group to the extent not related to the Program Business or of Paris and its Affiliates. Prior to the Closing, the Sellers and the members of the Company Group, as applicable, shall exercise, consistent with the terms and conditions of this Agreement, complete unilateral control and supervision over their business and operations, including the Program Business.

6.3 Confidentiality.

(a) The Parties acknowledge that the Buyer and Roivant Sciences, Inc. have previously executed a confidentiality agreement, dated as of January 18, 2023 (the "Confidentiality Agreement"), which Confidentiality Agreement shall continue in full force and effect in accordance with its terms, except as expressly modified herein or as the Buyer and Rome may mutually amend, supplement or otherwise modify from time to time. Effective upon the Closing, the Confidentiality Agreement shall terminate solely with respect to information relating to the Company Group or the Program Business (it being understood that any other information will continue to be subject to the provisions of the Confidentiality Agreement in accordance with its terms).

(b) For a period of five years from the Closing Date (except with respect to trade secrets, in which case the obligation shall survive for so long the trade secret is maintained as a trade secret under applicable Law), Rome shall, and shall cause its Affiliates to, hold in confidence nonpublic information that is proprietary or competitively sensitive ("Sensitive Business Information") to the extent relating to the Program Business; provided that the foregoing restriction shall not apply to information (i) that becomes available on a non-confidential basis to Rome or any of its Affiliates from and after the Closing from a third-party source that is not known by Rome or its applicable Affiliates after reasonable inquiry to be under any obligations of confidentiality to the Buyer or the Company Group with respect to such information, (ii) that is in the public domain or enters into the public domain other than as a result of breach by Rome or any of its Affiliates of the terms of this Agreement, (iii) to the extent used by Rome or any of its Affiliates to comply with the terms of this Agreement or any other Contract between Rome or any of its Affiliates, on the one hand, and the Company or any of its Affiliates, on the other hand, but for such purpose only, (iv) that is, following the Closing, independently developed or derived by Rome or any of its Affiliates without use of such Sensitive Business Information or (v) that Rome or any of its Affiliates is required by Law or required or requested pursuant to legal or regulatory process to disclose. In the event that Rome or any of its Affiliates is required by Law or required or requested pursuant to legal or regulatory process to disclose such Sensitive Business Information, Rome shall reasonably promptly notify the Buyer in writing (unless not permitted by Law or such legal or regulatory process to so notify), and the extent of the required or requested disclosure, and will use commercially reasonable efforts to cooperate with the Buyer, at the Buyer's sole cost and expense, to preserve to the extent reasonably practicable the confidentiality of such information; provided that Rome and its Affiliates may only disclose such Sensitive Business Information which, based on the advice of their respective legal counsel, is required by Law or such legal or regulatory process to be disclosed.

6.4 Key License Agreements. During the Pre-Closing Period, Rome shall take all actions within its control to cause the Company Group not to (a) amend, modify, assign, delegate (other than a limited delegation of obligations by way of subcontracting arrangements with existing subcontractors entered into in the Ordinary Course and in accordance with past practice), terminate or waive any provision of the Paris License Agreement (other than amendments or modifications that are solely ministerial or otherwise do not adversely affect the Company Group's rights thereunder, of which Buyer shall be given reasonable notice and an opportunity to comment within a reasonable timeframe (not to exceed five Business Days)) or (b) to the extent it has a consent right with respect thereto, permit any amendment, modification, termination or waiver of any [***] (other than amendments or modifications that are solely ministerial or otherwise do not adversely affect the Company Group's rights thereunder, of which Buyer shall be given reasonable notice and an opportunity to comment within a reasonable timeframe (not to exceed five Business Days)). For the avoidance of doubt, nothing in this Section 6.4 shall restrict Telavant from exercising the Option for the Bispecific Antibody (each, as defined in the Paris License Agreement) under the Paris License Agreement; provided that, notwithstanding the foregoing, Telavant shall not amend the Paris License Agreement to effect, or otherwise in connection with, its exercise of the Option for the Bispecific Antibody without the Buyer's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed).

ARTICLE VII.
ADDITIONAL AGREEMENTS

7.1 Access to Information; Development Plan.

(a) During the Pre-Closing Period, the Company and Rome shall afford to the Buyer's Representatives reasonable access, upon reasonable advance notice, during normal business hours and in a manner that does not materially disrupt or interfere with business operations, to all of the properties, books, Contracts, personnel and records of the Rome Group solely to the extent relating to the Company Group or the Program Business as the Buyer shall reasonably request in connection with the Acquisition, and, during such period, Rome and the Company shall furnish promptly to the Buyer such information concerning the business, properties, assets and personnel of the Company Group and the Program Business as the Buyer may reasonably request, solely for purposes of furthering the Acquisition, including for purposes of integration planning relating to the Acquisition.

(b) Without limiting the generality of the foregoing, Rome covenants and agrees that, during the Pre-Closing Period, it shall keep the Buyer reasonably informed, with respect to the Program Business and Program Products, as to the Rome Group's regulatory strategy, material communications with Regulatory Authorities and submissions to Regulatory Authorities, including by providing copies of material information to the Buyer. In order to keep the Buyer reasonably informed regarding its regulatory relationship with Regulatory Authorities for the Program Business and Program Products, Rome also agrees to cause the Rome Group to promptly provide the Buyer with any and all material communications with Regulatory Authorities for the Program Business and Program Products with respect to its submissions and other non-immaterial regulatory issues such as INDs and Clinical Trials (whether new or ongoing). Without limiting the generality of the foregoing, the Buyer shall have the right to, at its sole election, participate in all meetings of the Rome Group with the FDA or any other Regulatory Authority with respect to the Program Business or Program Products (whether in-person or via video or teleconference) and all material preparatory, follow-up and debrief meetings or conferences (including by telephone with respect thereto). Nothing contained in this Section 7.1(b) is intended to give the Buyer, directly or indirectly, the right to control or direct the regulatory strategy of the Program Business prior to the Closing Date.

(c) Rome and the Company covenant and agree that, during the Pre-Closing Period, the Company shall (i) not amend, in any material respect, the Development Plan without the Buyer's prior written consent (not to be unreasonably withheld, conditioned or delayed), except that such consent shall not be required (but Buyer shall be offered a reasonable time, not to exceed five Business Days, to comment thereupon, and the Company shall consider in good faith incorporating such comments) with respect to any such amendment that is mandated or recommended by a Regulatory Authority and (ii) keep the Buyer reasonably informed as to the Rome Group's progress of the material activities under the Development Plan, including material Regulatory Authority interactions and material correspondences and providing copies of final clinical data with respect to any Program Compound or Program Product that first becomes available to the Rome Group during the Pre-Closing Period. Nothing contained in this Section 7.1(c) is intended to give the Buyer, directly or indirectly, the right to control or direct the Development of the Program Compounds or Program Products prior to the Closing.

(d) Notwithstanding anything in the foregoing, no member of the Rome Group shall be required to provide access to or disclose any such information under this Section 7.1 (i) to the extent such access or disclosure would jeopardize or reasonably be expected to result in the loss of attorney-client privilege, attorney-work product protection or other legal privilege of the Rome Group or (ii) which is prohibited under applicable Law or Order or the terms of any agreement to which the Rome Group is a party as of the Effective Date; provided that Rome shall cause the Rome Group to cooperate in good faith to provide, to the extent feasible, substantially the information the Buyer requests in such a manner as not to waive any attorney-client or other legal privilege or contravene any applicable Law.

(e) Until the Closing, all information provided to the Buyer and its officers, employees, accountants, counsel and other Representatives shall be subject to the Confidentiality Agreement.

(f) If Closing occurs prior to the occurrence of the meeting described on Section 7.1(f)(1) of the Company Disclosure Schedule (the "Rome FDA Meeting"), then Rome shall provide Buyer and the Company with reasonable assistance with respect to the Rome FDA Meeting, including by making available to the Buyer the individuals listed on Section 7.1(f)(2) of the Company Disclosure Schedule (the "Continuing Employees") for the purpose of preparing for and attending the Rome FDA Meeting and handling any post-meeting follow-up. In furtherance thereof, and without limitation to Section 7.10(a), the Rome Group shall (i) from the date of this Agreement through immediately prior to the Closing, use its commercially reasonable efforts to continue the employment of the Continuing Employees, and (ii) from immediately prior to the Closing through the date that is five days following the Rome FDA Meeting and, at Buyer's sole election provided by notice in writing to Rome during such five day period immediately following the Rome FDA Meeting, for a period of up to five weeks after the date of the Rome FDA Meeting (such period, as applicable, the "Continuing Assistance Period"), use its commercially reasonable efforts to (A) continue the employment of the Continuing Employees who are employees of the Rome Group (other than the Company Group) and (B) engage as consultants the Continuing Employees who are Company Group Employees.

7.2 Consents and Antitrust Approvals.

(a) Subject to the terms and conditions of this Agreement, including Section 7.2(b), each Party shall, and each shall cause its Affiliates to and Rome shall cause the Company Group to, use their respective reasonable best efforts (unless, with respect to any action, another standard of performance is expressly provided for herein) to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable, to the extent permitted by applicable Law, to achieve satisfaction of the conditions to the Acquisition set forth in Article VIII and to consummate the Acquisition (in each case, no later than the End Date), including (x) preparing and filing as promptly as reasonably practicable with any Governmental Authority or other Third Party all documentation to effect all Filings (and thereafter make any other required or appropriate submissions) as are necessary to consummate the Acquisition, including (in each case as promptly as reasonably practicable) (A) Rome and the Buyer each making an appropriate Filing of a notification and report form pursuant to the HSR Act with the FTC and the Antitrust Division of the DOJ with respect to the Acquisition no later than ten (10) days after the date of this Agreement, (B) in relation to the Clearances set forth in Section 8.1(a) of the Company Disclosure Schedule, the Buyer preparing and filing a briefing paper with any Governmental Authority set forth in Section 8.1(a) of the Company Disclosure Schedule no later than ten (10) Business Days after the date of this Agreement and (C) Rome and the Buyer each making any other Filing that is required under any Antitrust Law (other than the HSR Act) or foreign investment Law, (y) using reasonable best efforts to obtain, and thereafter maintain, all Clearances required to be obtained from any Governmental Authority or other Third Party that are necessary to consummate the Acquisition, and complying with the terms and conditions of each Clearance (including by using reasonable best efforts to supply any additional information that may be required or reasonably requested pursuant to the HSR Act or other applicable Antitrust Laws or foreign investment Laws), and (z) using reasonable best efforts to cooperate, to the extent reasonable, with the other Parties in their efforts to comply with their obligations under this Agreement, including in seeking to obtain any required Clearances. Each of the Buyer and Rome (but not, for clarity, Paris) shall contest, defend and appeal any Action, whether judicial or administrative, challenging this Agreement or the consummation of the Acquisition. For the avoidance of doubt, except as expressly permitted in Section 7.2(a)(x)(B) above, no Party or its Affiliates shall be permitted, unless otherwise mutually agreed between Buyer and Rome, to submit a briefing paper to a Governmental Authority (including any Governmental Authority set forth in Section 8.1(a) of the Company Disclosure Schedule); provided that nothing in this Section 7.2(a) shall restrict the right of the Buyer to communicate (orally or in writing) with any Governmental Authority in response to prior communications or engagement from such Governmental Authority with Buyer, Rome or their respective Affiliates.

(b) Notwithstanding the foregoing, or anything else in this Agreement, Buyer shall not be required to (A) divest, sell, license or otherwise dispose of, subject to a hold-separate order or other restriction with respect to any asset, operation, division, business, product line or business relationship of the Buyer or its Affiliates or the Company Group, (B) terminate, amend or assign existing relationships or contractual rights or obligations or (C) amend, assign or terminate existing licenses or other agreements or enter into new licenses or other agreements, in any such case to obtain the expiration of any applicable waiting period or clearance with respect to the Clearances (each, a "Burdensome Condition").

(c) Subject to the Buyer's overall control of strategy (including with respect to communications and timing matters related to interactions with the applicable Governmental Authority, but subject to the express rights of Rome and the Company set forth in this Section 7.2 and the express timing limitations set forth in Section 7.2(a)(x)) with respect to the Parties' efforts to obtain the Clearances, the Buyer and the Company shall cooperate in good faith (including the Buyer reasonably consulting with and considering in good faith all comments and advice of Rome and its counsel), to jointly develop, devise and implement the strategy for obtaining any necessary approval of, for responding to any request from, inquiry or investigation by (including with respect to the timing, nature and substance of all such responses), and shall jointly participate in all meetings and communications (including any negotiations) with, any Governmental Authority that has authority to enforce any Antitrust Law or foreign investment Law. The Buyer shall control the defense and settlement of any Action brought by or before any Governmental Authority that has authority to enforce any Antitrust Law or foreign investment Law; provided that the Buyer shall reasonably consult with and consider in good faith all comments and advice of Rome and its counsel in respect of such Action. None of the Buyer, Rome, the Company or any of their respective Affiliates shall (x) commit to or agree with any Governmental Authority to stay, toll or extend any applicable waiting period under the HSR Act or any other Antitrust Laws or enter into a timing agreement with a Governmental Authority, or (y) withdraw and refile its initial filing pursuant to the HSR Act or any other Antitrust Law, as the case may be, without the prior written consent of Rome and Buyer, not to be unreasonably withheld, conditioned or delayed.

(d) To the extent permitted by applicable Law, each of the Parties shall, and shall cause its Affiliates to, as promptly as practicable, (i) upon request from a Governmental Authority, furnish to such Governmental Authority any information or documentation concerning themselves, their Affiliates, directors, officers and stockholders, information or documentation concerning the Acquisition and information or documentation on such other matters as may be requested and (ii) make available their respective directors, officers, employees, agents, investment bankers, financial advisors, legal advisors, accountants, brokers, finders, consultants or other representatives ("Representatives") to, upon reasonable request, any Governmental Authority, in the case of each of clause (i) and (ii), in connection with (A) the preparation of any Filing made by or on their behalf to any Governmental Authority in connection with the Acquisition or (B) any Governmental Authority investigation, review or approval process.

(e) Subject to Section 7.2(b), applicable Laws relating to the sharing of information and the terms and conditions of the Confidentiality Agreement, and subject to the proviso at the end of this Section 7.2(e), each of Parties shall, and each shall cause its Affiliates to, and Rome shall cause the Company Group to (i) (A) as far in advance as practicable, notify the other Party of, and provide the other Party with an opportunity to consult with respect to, any Filing or material or substantive communication or inquiry it or any of its Affiliates or the Company Group intends to make with any Governmental Authority relating to the matters that are the subject of this Agreement, (B) prior to submitting any such Filing or making any such communication or inquiry, the submitting or making Party shall provide the other Party and its respective counsel a reasonable opportunity to review, and shall consider in good faith the comments of the other Party and such Party's Representatives in connection with any such Filing, communication or inquiry, and (C) promptly following the submission of such Filing or making of such communication or inquiry, provide the other Party with a copy of any such Filing or, if in written form, a summary of any communication or inquiry, (ii) as promptly as practicable following receipt, furnish the other Party with a copy of any Filing or, if in written form, material or substantive communication or inquiry, it or any of its Affiliates or the Company Group receives from any Governmental Authority relating to matters that are the subject of this Agreement and (iii) coordinate and reasonably cooperate with the other two Parties in exchanging such information and provide such other assistance as the other two Parties may reasonably request in connection with this Section 7.2; provided that the Buyer, Paris and Rome may limit provision of such information to outside counsel to each of the other two Parties and may redact information that is covered by the attorney-client privilege or relates to the valuation of the Acquisition. Subject to Section 7.2(b), none of the Parties or their respective Affiliates or Representatives shall agree to participate in any material or substantive meeting or conference (including by telephone) with any Governmental Authority, or any member of the staff of any Governmental Authority, in respect of any Filing, Action (including the settlement of any investigation) or other inquiry regarding the Acquisition unless it consults with Rome and the Buyer in advance and, to the extent permitted by such Governmental Authority, allows (i) in the case of a meeting or conference involving Rome or the Company or their respective Representatives, the Buyer to participate and (ii) in the case of a meeting or conference involving the Buyer or its Representatives, Rome to participate.

(f) Except as set forth in Section 7.2(f) of the Company Disclosure Schedule, the Buyer shall not (and shall cause its Affiliates not to) acquire or agree to acquire (by merging or consolidating with, or by purchasing a substantial portion of the assets of or equity in, or by any other manner), any Person or portion thereof, if the entering into an agreement relating to, or the consummation of, such acquisition, merger or consolidation would reasonably be expected to prevent or materially delay the consummation of the Acquisition on or prior to the End Date.

(g) Each Party agrees to cooperate and Rome shall use commercially reasonable efforts in obtaining any consents and approvals of Third Parties that may be required in connection with the transactions contemplated by this Agreement pursuant to the Material Contracts set forth on Section 4.6(a) of the Company Disclosure Schedule. Notwithstanding anything to the contrary in this Agreement, nothing herein shall obligate or be construed to obligate any member of the Company Group to make, or to cause to be made, any payment to any Third Party in order to obtain the consent or approval of such Third Party under any contract or otherwise. Notwithstanding anything to the contrary in this Agreement, Buyer agrees that none of the Sellers or any of their respective Affiliates shall have any liability whatsoever to Buyer arising out of or relating to the failure to obtain any such consent and no representation, warranty or covenant herein shall be breached or deemed breached, no condition shall be deemed not satisfied and no termination right shall be deemed triggered as a result of such failure.

(h) In the event of any Willful Breach by a controlling Affiliate of the Buyer (solely for these purposes, as though such Affiliate were a party to this Agreement) of any provision of this Section 7.2 applicable to the Buyer's Affiliates, such Willful Breach shall be deemed to be a Willful Breach of the Buyer for all purposes of this Agreement.

7.3 Notice of Certain Events. The Sellers and the Company shall give notice to the Buyer and the Buyer shall give notice to Rome, as promptly as reasonably practicable upon becoming aware of the institution of, or the threat of institution of, any Action against it or any of their respective Affiliates related to this Agreement or the transactions contemplated hereby; provided that any failure to give notice in accordance with the foregoing shall not, in and of itself, be deemed to constitute the failure of any condition set forth in Section 8.2(b) or Section 8.3(b), as applicable, to be satisfied. The delivery of any notice pursuant to this Section 7.3 shall not limit or otherwise affect the remedies available hereunder to the Party receiving such notice, or the representations or warranties of, or the conditions to the obligations of, the Parties.

7.4 Public Disclosure.

(a) Subject to Section 6.3, (i) Rome and the Company shall reasonably consult with the Buyer, and the Buyer shall reasonably consult with Rome, before issuing any press release or otherwise making any public statement or making any other public disclosure (whether or not in response to an inquiry) regarding the terms of this Agreement and the transactions contemplated hereby, and (ii) no Party or its Affiliates shall issue any such press release or make any such public statement or disclosure without the prior written approval of the Buyer (in the case of any other Party) or Rome (in the case of any other Party), except as permitted by Sections 7.4(b); provided, however, that the Parties may make public statements or disclosures that are not inconsistent with (or more expansive than) previous press releases, public disclosures or public statements made by the Parties in compliance with this Section 7.4.

(b) Each Party may disclose such information as may be required by applicable Law or Order, including those incident to the listing of securities on a stock exchange or governing disclosure of publicly traded companies in the United States, without the consent of the other Parties; provided, further, that the Party disclosing such information shall (i) only disclose such information as is required by such applicable Law or Order; and (ii) provide reasonable advance notice to the extent practicable to the Buyer (in the case of Rome, Paris and the Company) or Rome (in the case of the Buyer) of the intended disclosure and the content of that disclosure and shall permit the Buyer (in the case of Rome, Paris and the Company) or Rome (in the case of the Buyer) the opportunity to comment on any such disclosure.

7.5 Non-Solicit. Without Rome's prior written consent, Buyer shall not, and shall cause its Affiliates (including after the Closing, the Company Group) not to, directly or indirectly, for a period of 12 months from and after the Closing Date, solicit for employment or services or hire any employee or service provider of the Rome Group as of the Closing that was involved in the operations of the Program Business or had first become known to Buyer in connection with its evaluation of the Acquisition or negotiation of the Agreement (each, a "Rome Covered Person"); provided that this Section 7.5 shall not preclude the Buyer and its Affiliates from (i) soliciting for employment or services any Rome Covered Person pursuant to a general solicitation through a public medium or general or mass mailing by or on behalf of the Buyer or its Affiliates that is not targeted at Rome Covered Persons or (ii) hiring any Rome Covered Person who ceases to be employed by the Rome Group (following the three-month anniversary of such Rome Covered Person ceasing to be so employed).

7.6 Retention of Records. Subject to any retention requirements relating to the preservation of Tax records, the Buyer and Rome agree that each of them shall (and shall cause the Company Group to) preserve and keep the records held by them relating to the Program Business for a period of seven years from the Closing Date, and shall make such records available during regular business hours on reasonable notice to the other as may be reasonably requested by such Party, at such Party's expense, in connection with, among other things, any insurance claims by, Actions against or by Governmental Authorities of, the Buyer, the Sellers or the Company Group, for Tax or accounting reasons, to enable the Buyer or Rome to comply with its obligations under this Agreement and each other agreement, document or instrument contemplated hereby or other reasonable need; provided, however, that none of the Buyer, Rome and the Company Group shall be required to afford such access or such information to the extent that doing so would result in the loss of attorney-client privilege, attorney work product protection or other legal privilege or to provide access to information that is pertinent to a dispute between the Buyer or its Affiliates, on the one hand, and the Rome Group, on the other hand.

7.7 Tax Matters.

(a) The Buyer and Rome shall provide each other with such reasonable cooperation and assistance as may be reasonably requested in writing by either of them in connection with the preparation of any Tax Return, any audit or other examination by any Tax Authority, or any judicial or administrative proceedings relating to liability for Taxes ("Tax Contests") of or relating to any member of the Company Group, provided that the Buyer and the Company shall in no event be required under this Section 7.7(a) to provide any information with respect to the Company Group or to cooperate hereunder with respect to Taxes, for any Tax Period, or portion of a Tax Period, beginning after the Closing Date except to the extent includable in the Tax Package; and provided that, the Buyer shall not be required under this Section 7.7(a) to provide any information of its operations or those of its Affiliates (other than for the Company Group as provided in this Section 7.7(a)). The Buyer shall cause the members of the Company Group to execute such Tax Returns, powers of attorney or both as Rome may reasonably request in connection with filing any Tax Return for a Pre-Closing Tax Period or Straddle Period that includes Rome or any of its Affiliates or Tax Contest with respect to Rome or any of its Affiliates, in each case other than Tax Returns or Tax Contests that relate solely to the Company Group. Within a reasonable period of time following the Closing Date, the Buyer shall prepare and provide, or cause to be prepared and provided, to Rome a Tax Package that includes all members of the Company Group whose Tax Period ended on the Closing Date (or otherwise as a result of the Closing) for any combined, consolidated, affiliated, unitary or similar Tax Returns. Rome will provide the Buyer with information reasonably requested by Buyer (i) in connection with the preparation or provision of the Tax Package and (ii) pertaining to the utilization of any Tax assets of the Company Group by any member of a Company/Rome Tax Group during the Pre-Closing Tax Period or Straddle Period. Notwithstanding anything in this Agreement to the contrary, neither the Buyer nor any of its Affiliates on the one hand or Rome or any of its Affiliates on the other hand, shall be required to provide to any Person any right to access or to review any Tax Return or Tax work papers of the Buyer or any of its Affiliates or Rome or any of its Affiliates, as applicable (including any consolidated, combined, affiliated or unitary Tax Return that includes the Buyer or any of its Affiliates or Rome or any of its Affiliates, as applicable, and any pro forma Tax Return used to create any such consolidated, combined, affiliated or unitary Tax Return), in each case other than information (i) necessary to comply with the preceding sentence (which may be provided on a pro forma basis) and (ii) solely related to the Company Group.

(b) For purposes of this Agreement, any Taxes of the Company Group with respect to any Straddle Period will be apportioned between the portion of such period up to and including the Closing Date (such portion, the Pre-Closing Tax Period of a Straddle Period) and the portion of such Straddle Period that begins after the Closing Date where the Pre-Closing Tax Period amount of a Straddle Period will be (i) in the case of any real or personal property or similar periodic Taxes, the amount of such Tax for the entire period multiplied by a fraction, the numerator of which is the number of days in the Pre-Closing Tax Period of a Straddle Period and the denominator of which is the number of days in such Straddle Period and (ii) in the case of any other Tax, the amount which would be payable if the relevant taxable period ended as of the close of business on the Closing Date. For purposes of this allocation, any exemption, deduction, credit or other item for a Straddle Period will be allocated in the same manner as described in the previous sentence. For the avoidance of doubt, nothing in this Section 7.7(b) shall affect the provisions of Section 7.10.

(c) Notwithstanding anything to the contrary in this Agreement, for any state or local consolidated, combined, unitary or similar group that includes or has included any member of the Company Group with any member of the Rome Group (a "Company/Rome Group," and such taxes of a Combined Company/Rome Group, "Combined Company/Rome Group Taxes"), (i) such member(s) of the Company Group shall be allocated, and shall be responsible for, the portion of such Combined Company/Rome Group Taxes that are properly attributable to such Company Group member(s), and (ii) such member(s) of the Rome Group shall be allocated, and shall be responsible for, the portion of such Combined Company/Rome Group Taxes such that are properly attributable to such Rome Group member(s). The Parties agree that to the extent Buyer or its Affiliates (including after the Closing, the Company Group) on the one hand, or Rome or its Affiliates, on the other hand, has an actual cash Tax liability for any Combined Company/Rome Group Taxes that are attributable to Rome or its Affiliates (other than the Company Group) or Buyer or its Affiliates (including, after the Closing, the Company Group), as applicable, Rome or Buyer, as applicable, shall reimburse the paying Party (or cause such paying Party to be reimbursed) for such Combined Company/Rome Group Taxes upon reasonable written request therefor; provided, that if such request is made within ten (10) Business Days prior to the due date (including extensions) for such Taxes, such payment shall be made in all cases at least three (3) Business Days prior to such due date.

(d) Buyer shall prepare all Pre-Closing Tax Period and Straddle Period Tax Returns with respect to a Company/Rome Group that are due after the Closing where the entity legally obligated to file such Tax Return is Buyer or any of its Affiliates (including the Company Group) (each a "Buyer Tax Return"); provided, that (A) such Buyer Tax Returns shall be prepared on a basis consistent with those prepared for prior taxable periods, if any, unless a different treatment of any item is required by applicable Law, (B) Buyer (1) shall provide a complete copy of such Buyer Tax Returns to Rome for its review and comment at least fifteen days prior to the due date for filing of such Buyer Tax Returns (including extensions) and (2) shall not file any such Buyer Tax Returns without first obtaining the prior written consent of Rome (not to be unreasonably withheld, conditioned or delayed); provided, that if Rome and Buyer have not agreed on a Buyer Tax Return by the due date of such Tax Return, then Buyer may file such Tax Return (as prepared by Buyer) when due and the Parties shall submit any disputes for resolution in accordance with the principles of Section 2.5(d) (*mutatis mutandis*) and Buyer shall amend such Tax Return as necessary to give effect to the final resolution of such dispute, and (C) Buyer shall timely file (or cause the Company Group to timely file) any such Buyer Tax Returns.

(e) Rome shall prepare and file any Tax Returns with respect to a Company/Rome Group that are due after the Closing where the entity legally obligated to file such Tax Return is Rome or any of its Affiliates (other than a member of the Company Group), including any state income Tax Return that is filed on a combined basis for or with respect to any Pre-Closing Tax Period, including any Straddle Period (each a "Rome Tax Return"); provided, that (A) such Rome Tax Returns shall be prepared on a basis consistent with those prepared for prior taxable periods, if any, unless a different treatment of any item is required by applicable Law, (B) Rome (1) shall provide a pro forma copy of such Rome Tax Returns reflecting only the items relating to the Company Group to Buyer for its review and comment at least fifteen days prior to the due date for filing of such Rome Tax Returns (including extensions) and (2) shall not file such Rome Tax Return without first obtaining the prior written consent of Buyer (not to be unreasonably withheld, conditioned or delayed); provided, that if Rome and Buyer have not agreed on a Rome Tax Return by the due date of such Tax Return, then Rome may file such Tax Return (as prepared by Rome) when due and the Parties shall submit any disputes for resolution in accordance with the principles of Section 2.5(d) (*mutatis mutandis*) and Rome shall amend such Tax Return as necessary to give effect to the final resolution of such dispute, and (C) Rome shall timely file (or cause to be timely filed) any such Rome Tax Returns. With respect to any Rome Tax Return, the Parties agree that Rome shall be entitled to claim on its combined Tax Return any exemption, deduction, credit or other item that would be allocated to the Pre-Closing portion of a Straddle Period under Section 7.7(b), and Buyer shall be entitled to claim any losses, credits, or other deductions that are attributable to the Company Group and are allocated to the portion of the Straddle Period that begins after the Closing Date.

(f) In the case of any Tax Contest that relates to a Company/Rome Group or Combined Company/Rome Group Taxes, Rome shall, at its cost and expense, have exclusive right to control such Tax Contest; *provided* that, if the settlement or other resolution of such Tax Contest would reasonably be expected to increase the amount of Taxes payable or borne by, or otherwise negatively affect the tax position of, the Buyer or its Affiliates, including the Company Group, then, to the extent related thereto, (i) the Buyer, at its sole cost and expense, shall have the right to participate in such audit or Tax proceeding and receive copies of all material correspondence with respect thereto and (ii) Rome shall not settle, compromise or otherwise resolve such Tax Contest without the Buyer's prior written consent, not to be unreasonably withheld, conditioned or delayed.

(g) Notwithstanding anything to the contrary herein, all transfer, documentary, sales, use, stamp, registration and other such Taxes, and all conveyance fees, recording charges and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated by this Agreement ("Transfer Taxes") shall be borne equally by the Sellers, on the one hand, and the Buyer, on the other hand. The Buyer and the Sellers shall cooperate in timely making all filings, returns, reports and forms as necessary or appropriate to comply with the provisions of all applicable Laws in connection with the payment of such Transfer Taxes and shall cooperate in good faith to minimize the amount of any such Transfer Taxes payable in connection herewith.

(h) Notwithstanding anything to the contrary herein, all Tax Sharing Agreements between any member of the Company Group, on the one hand, and any Person (other than any member of the Company Group), on the other hand, shall be terminated prior to the Closing Date and, after the Closing, no member of the Company Group will be bound thereby or have any liability thereunder.

(i) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of this Section 7.7 shall survive until sixty days after the expiration of the statute of limitations with respect to the relevant Tax (taking into account any extension, mitigation or waiver thereof).

7.8 Affiliate Matters. On or prior to the Closing Date, except as expressly contemplated by this Agreement or as set forth in Section 7.8 of the Company Disclosure Schedule, all Contracts between the Rome Group, on the one hand, and the Company Group, on the other hand, and all Intercompany Obligations shall be settled or otherwise eliminated or terminated, as applicable, in each case, effective as of the Closing, with no consideration payable by any Party in respect thereof or any continuing liability of any Party thereunder.

7.9 Release.

(a) Effective as of the Closing, each Seller, on behalf of itself and each of its Affiliates, or any Person claiming by, through or for the benefit of any of them, and each of their respective successors and assigns, hereby irrevocably, unconditionally and completely waives and releases and forever discharges Buyer and its Affiliates and each member of the Company Group and each of their respective heirs, executors, administrators, successors and assigns (such released Persons, the "Transferred Releasees"), in each case from all claims arising solely in such Seller's capacity as a stockholder of the Company whatsoever of every name and nature, both in law and in equity, arising out of or related to events, circumstances or actions taken by the Transferred Releasees occurring or failing to occur, in each case, at or prior to the Closing, other than in each case, (i) any rights of either Seller, its Affiliates and their respective Representatives under this Agreement or any other written agreement to be in effect between such Seller and the Company (or their respective Affiliates) after the Closing, or any enforcement thereof, (ii) accounts payable set forth in Section 7.8 of the Company Disclosure Schedule, (iii) the rights of Sellers and their Affiliates under the terms of the Paris Transaction Agreements that by their terms survive the Closing, (iv) the other arrangements, understandings or Contracts listed in Section 7.8 of the Company Disclosure Schedule or (v) Fraud. Each Seller shall not make, and each Seller shall not permit any of its Affiliates to make, and each Seller covenants never to, and to cause its Affiliates not to, assert or voluntarily assist any Person in asserting any claim, or commence any Action asserting any claim, including any claim for contribution or indemnification, against any of the Transferred Releasees with respect to any claims released pursuant to this Section 7.9(a).

(b) Effective as of the Closing, the Buyer, on behalf of itself and each of its Affiliates (including the Company Group), or any Person claiming by, through or for the benefit of any of them, and each of their respective successors and assigns, hereby irrevocably, unconditionally and completely waives and releases and forever discharges each Seller and its Affiliates and each of their respective heirs, executors, administrators, successors and assigns (such released Persons, the "Selling Releasees"), in each case from all claims arising whatsoever of every name and nature, both in Law and in equity, arising out of or related to the Sellers' ownership or operation of the Company Group or the Program Business at or prior to the Closing, other than in each case, (i) any rights of the Buyer, its Affiliates and their respective Representatives under this Agreement, the Paris License Agreement or any other written agreement to be in effect between the Buyer and the Company (or their respective Affiliates) after the Closing, or any enforcement thereof, (ii) accounts payable set forth in Section 7.8 of the Company Disclosure Schedule, (iii) the other arrangements, understandings or Contracts listed in Section 7.8 of the Company Disclosure Schedule or (iv) Fraud. The Buyer shall not make, and the Buyer shall not permit any of its Affiliates to make, and the Buyer covenants never to, and to cause its Affiliates not to, assert or voluntarily assist any Person in asserting any claim, or commence any Action asserting any claim, including any claim for contribution or indemnification, against any of the Selling Releasees with respect to any claims released pursuant to this Section 7.9(b).

7.10 Employee Matters.

(a) Immediately prior to, and contingent upon the Closing, the Company Group shall terminate (x) the employment of each Company Group Employee and (y) unless otherwise requested in writing by Buyer prior to the Closing, each consulting agreement between a member of the Company Group and each Company Group Service Provider. The Company Group shall provide each Company Group Employee whose employment is terminated pursuant to this Section 7.10(a) (a "Terminated Employee") and who executes and does not revoke a release of claims prepared by Rome, which release shall cover all claims against the Sellers, the Company Group and the Buyer and their respective Affiliates (each, a "Release"), in a form agreed to by each of the foregoing, with severance benefits equal to a cash amount equal to the sum of (i) the greater of (A) the amount of cash severance payments such Terminated Employee is entitled to under any Company Benefit Plan (the amount of cash severance described in this clause (A), the "Contractual Cash Severance") and (B) three months of such Terminated Employee's base salary payable by the Company Group (which cash amount shall be determined (x) with respect to each Terminated Employee who was a Company Group Employee as of the Effective Date (each such Terminated Employee, a "Current Employee") based on such Current Employee's hourly wage or base salary (as applicable) payable by the Company Group in effect as of the Effective Date and (y) with respect to each Terminated Employee who is not a Current Employee (each such Terminated Employee, a "New Hire") based on such New Hire's initial base salary payable by the Company Group) (the amount of cash severance described in this clause (B), the "Section 7.10(a) Cash Severance") and (ii) an amount, determined on a post-tax basis, equal to the cost to such Terminated Employee for continued coverage for such Terminated Employee (and such Terminated Employee's covered dependents, if applicable) under the Company's group health plans under Section 4980B of the Code (including the portion of the premium that the Company subsidized for active employees and a 2% administrative fee) for three months at the same levels and costs as in effect on the date of termination of employment (the sum of the amounts in (i) and (ii), the "Severance Obligations"), payable in accordance with Section 7.10(b).

(b) The Buyer shall cause the Company Group to pay the Severance Obligations, the Accrued Bonus Amounts and the Approved 280G Gross-up Payments to the respective Terminated Employees and other Company Group Service Providers, in each case subject to the applicable Terminated Employee's or Company Group Service Provider's execution and non-revocation of a Release, with each such payment to be made in a lump sum to the Terminated Employee or Company Group Service Provider entitled to such payment on the first payroll date immediately following the date that such Terminated Employee or Company Group Service Provider's Release becomes effective and irrevocable. No later than ten days prior to the Closing, Rome shall provide to Buyer (or its counsel) (i) a true and complete schedule that sets forth each of the Approved 280G Gross-up Payments for each applicable Company Group Service Provider and the related 280G calculations prepared by KPMG LLP and (ii) a true and complete schedule of the Accrued Bonus Amount for each Company Group Employee.

(c) Rome shall assume or retain sponsorship of and be solely responsible for, and shall indemnify and hold the Buyer and its Affiliates harmless for, (i) all Liabilities and obligations relating to or at any time arising under or in connection with any Benefit Plan, and (ii) all Liabilities based upon, relating to or arising from the employment or services, or the termination of employment or service (actual or constructive), of any Company Group Service Provider or any other current or former employee or service provider of Rome and its Affiliates, in each case whether arising prior to, on, or after the Closing Date (including, without limitation, any severance or termination-related payments or benefits and including any such Liabilities arising under applicable Law) but other than any Liabilities that relate to any services performed for the Buyer and its Affiliates following the Closing (other than any Liabilities for the services contemplated in Section 7.1(f) during the Continuing Assistance Period), in each case other than (x) any Liabilities included in Transaction Expenses, Indebtedness or in Closing Net Working Capital, (y) any Approved 280G Gross-up Liabilities, Severance Obligations or Accrued Bonus Amounts (the bearing of Liability for each of which is otherwise addressed in this Agreement) and (z) the loss of any deduction or other tax benefit as a result of the application of Section 280G of the Code.

(d) Prior to the Closing, the Company Group shall take (or cause to be taken) all actions necessary to terminate or transfer to the Rome Group (other than the Company Group), effective as of immediately prior to the Closing, (i) all Company Benefit Plans, (ii) any relationship of the Company Group with any professional employer organization and (iii) the participation in any Benefit Plan by any member of the Company Group.

(e) Nothing in this Section 7.10 shall (i) be construed as an amendment or other modification of, or the establishment or termination of, any Company Benefit Plan, Benefit Plan or other benefit or compensation plan, agreement or arrangement, (ii) obligate Buyer or any of its Affiliates to retain the employment of any particular employee of the Company or any of its Subsidiaries following the Closing, (iii) give any Third Party any right to enforce the provisions of this Agreement or any remedies under this Agreement or (iv) limit the right of any member of the Rome Group or the Buyer and its Affiliates to amend, terminate or otherwise modify any Company Benefit Plan, Benefit Plan or other benefit or compensation plan, agreement or arrangement.

7.11 Directors & Officers Indemnification.

(a) The Buyer shall cause each member of the Company Group to honor and fulfill, in all respects, the obligations of the Company Group pursuant the Constitutive Documents of each member of the Company Group, the Investor Rights Agreement and to any indemnification agreement between the Company Group, on the one hand, and any of its current or former directors, managers, officers or employees (each, an "Indemnified Party" and collectively, the "Indemnified Parties"), on the one hand, for any act or omission by any such Indemnified Party occurring prior to the Closing. In addition, during the period commencing at the Closing and ending on the sixth anniversary of the Closing, the Buyer shall cause each member of the Company Group to cause the Constitutive Documents of such member of the Company Group to contain provisions with respect to indemnification, exculpation and the advancement of expenses that are at least as favorable as the indemnification, exculpation and advancement of expenses provisions set forth in the Constitutive Documents of each such member of the Company Group as of the Effective Date. During such six-year period, such provisions may not be repealed, amended or otherwise modified in any manner except as required by applicable Law. Without limiting the generality of the foregoing provisions of this Section 7.11(a), following the Closing, the Buyer shall, and shall cause each member of the Company Group to, defend, indemnify and hold harmless, to the fullest extent permitted by applicable Law, each Indemnified Party with respect to such member from and against any cost, fee and expense (including attorneys' fees and investigation expenses), judgment, fine, loss, claim, damages, liability and amount paid in settlement or compromise in connection with any Action to the extent that such Action arises, directly or indirectly, out of or pertains, directly or indirectly, to (i) any action or omission, or alleged action or omission, in such Indemnified Party's capacity as a director, manager, officer, employee or agent of such member of the Company Group to the extent that such action or omission, or alleged action or omission, occurred prior to or at the Closing or (ii) any of the transactions contemplated by this Agreement.

(b) On the Closing Date, the Buyer shall pay for a non-cancelable run-off insurance policy of not less than the existing coverage amount, for a period of six years from and after the Closing Date to provide insurance coverage for events, acts or omissions occurring on or prior to the Closing Date for all of the Indemnified Parties on or prior to the Closing Date (the "D&O Insurance"), which policy shall contain terms and conditions no less favorable to the insured persons than the directors', managers' or officers' liability coverage presently maintained by each member of the Company Group; provided however that if such insurance policy is not available at an annual cost not greater than the amount set forth on Section 7.11(b) of the Company Disclosure Schedule, (the "Insurance Cap"), then Buyer shall maintain, or shall cause the Company Group to maintain, as much comparable insurance as can reasonably be obtained in Buyer's good faith judgment at a cost up to but not exceeding the Insurance Cap.

(c) The covenants contained in Section 7.11(a) are intended to be for the benefit of, and shall be enforceable by, each of the Indemnified Parties and their respective heirs and legal representatives and shall not be deemed exclusive of any other right to which an Indemnified Party is entitled, whether pursuant to Law, Contract or otherwise. In the event that the Buyer, any member of the Company Group or any of their respective successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation, company or entity of such consolidation or merger or (ii) transfers or conveys all or substantially all of its properties and assets to any Person, then, and in each such case, proper provision shall be made so that the successors, assigns or transferees of the Buyer or any member of the Company Group, as the case may be, shall succeed to the obligations set forth in Section 7.11(a).

7.12 Paris Transaction Agreements. The Parties agree that nothing in this Agreement shall require Rome or the Company to take any action or not take any action that would conflict with the express rights of Paris under any of the Paris Transaction Agreements and, in the event of any such conflict, the Parties will work in good faith to make such commercially reasonable adjustments to the terms of this Agreement as are necessary to eliminate any such conflict (it being understood that no such adjustment shall alter in any material respect the material rights or obligations of any Party or the benefits expected to be derived from the transactions contemplated hereby by any Party).

7.13 Post-Closing Arrangements. Immediately following the Closing, the Buyer shall cause the Company to duly execute and deliver such documents that are reasonably requested by Rome to terminate the Equity Commitment Letter, and following the Closing until the time of such termination, the Buyer shall cause the Company not to draw down or accept any amounts committed under the terms of the Equity Commitment Letter (and if the Company does so, the Buyer shall cause the Company to promptly return such funds to Rome, without any interest).

7.14 Drag-Along. Within 10 Business Days after the Effective Date, Rome shall deliver to Paris the Drag-Along Sale Notice referred to in Section 2.3(d) of the ROFR and Co-Sale Agreement with respect to the transactions contemplated by this Agreement. Rome shall use its commercially reasonable efforts to procure that Paris shall execute and deliver the Joinder Agreement, as promptly as practicable after the Effective Date. Upon execution and delivery of the Joinder Agreement, Paris shall become a Seller and a Party hereunder solely with respect to the specific provisions of this Agreement set forth in the Joinder Agreement.

7.15 Trademark Phase-Out. As soon as reasonably practicable following the Closing Date (and in any event, within thirty days of the Closing Date), Rome shall, and shall cause each member of the Rome Group, to cease any and all use of the Telavant Trademarks. Notwithstanding the foregoing, nothing herein shall prevent or restrict the Rome Group from using the Telavant Trademarks following the Closing Date: (a) as required by applicable Law or Order, including those incident to the listing of securities on a stock exchange or governing disclosure of publicly traded companies in the United States; or (b) on its website or other public-facing documents or other materials, in each case as reasonably necessary to accurately describe the Rome Group's historical relationship with the Company Group.

ARTICLE VIII.
CONDITIONS TO ACQUISITION

8.1 Conditions to Each Party's Obligation to Effect the Acquisition. The respective obligations of each Party to this Agreement to consummate the Acquisition shall be subject to the satisfaction or waiver (to the extent permitted by Law) in writing by the Parties entitled to the benefit of such condition, at or prior to the Closing, of the following conditions:

(a) Antitrust Approvals. (i) The waiting period (and any extension thereof) applicable to the consummation of the Acquisition under the HSR Act shall have expired or been terminated, (ii) any agreement with a Governmental Authority entered into in accordance with Section 7.2 not to consummate, or to delay consummation, of the Acquisition shall have expired or been terminated and (iii) the Clearances set forth in Section 8.1(a) of the Company Disclosure Schedule shall have been obtained, as applicable, in the case of each of clauses (i), (ii) and (iii) without the imposition by the applicable Governmental Authority of a Burdensome Condition (other than a Burdensome Condition that Buyer (in its sole discretion) has determined to accept).

(b) Legal Restraints. No Governmental Authority of competent jurisdiction shall have (i) issued any Order (whether preliminary or permanent) or (ii) enacted any Law after the Effective Date, in each case that (x) remains in effect (or would become effective upon the Closing) and makes illegal or otherwise prohibits consummation of the Acquisition or (y) imposes a Burdensome Condition that Buyer has not (in its sole discretion) determined to accept (collectively, "Legal Restraints").

8.2 Additional Conditions to Obligations of the Buyer. The obligation of the Buyer to consummate the Acquisition shall be subject to the satisfaction or waiver (to the extent permitted by Law) in writing by the Buyer, at or prior to the Closing, of each of the following additional conditions:

(a) Representations and Warranties.

(i) The representations and warranties of the Sellers and the Company set forth in this Agreement, as applicable (other than any Fundamental Representations and the representations and warranties set forth in Section 3.3 and 4.8(b)), shall be true and correct in all respects as of the Closing Date as though made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case the accuracy of such representations and warranties shall be determined as of such date), and without regard to any materiality, Business Material Adverse Effect or Seller Material Adverse Effect qualifications contained therein, except where the failure of such representations and warranties to be so true and correct would not reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect, in the case of the representations and warranties set forth in Article III, or a Business Material Adverse Effect, in the case of the representations and warranties set forth in Article IV;

(ii) the representations and warranties set forth in Section 3.3 shall be true and correct in all respects (other than *de minimis* respects) as of the Closing Date as though made on and as of each such date;

(iii) the representation and warranty set forth in Section 4.8(b) shall be true and correct in all respects as of the Closing Date as though made on and as of each such date; and

(iv) the Fundamental Representations shall be true and correct (A) in all respects, in the case of any such Fundamental Representations that are qualified within the text thereof by any materiality, Business Material Adverse Effect or Seller Material Adverse Effect qualifications or (B) in all material respects, in the case of any such Fundamental Representations that are not so qualified within the text thereof by any such materiality, Business Material Adverse Effect or Seller Material Adverse Effect qualifications, in each case as of the Closing Date as though made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case the accuracy of such representations and warranties shall be determined as of such date).

(b) Performance of Obligations of the Sellers and the Company. Each of the Sellers and the Company shall have performed or complied in all material respects with all agreements and covenants required to be performed by or complied with by it under this Agreement on or prior to the Closing Date.

(c) Officer's Certificate. The Buyer shall have received a certificate, dated as of the Closing Date and (i) signed on behalf of Rome by an officer of Rome, stating that the conditions specified in Section 8.2(a) and Section 8.2(b) (insofar as such representations and warranties are made by, or the relevant covenants apply to, Rome) have been satisfied and (ii) signed on behalf of Paris by an officer of Paris (or an agent of Paris), stating that the conditions specified in Section 8.2(a) and Section 8.2(b) (insofar as such representations and warranties are made with respect to, or the relevant covenants apply to, Paris) have been satisfied.

(d) Seller and Company Deliveries. The Buyer shall have received all of the instruments, documents and considerations described in Section 2.6.

8.3 Additional Conditions to Obligations of the Company and the Sellers. The obligation of the Company and the Sellers to consummate the Acquisition shall be subject to the satisfaction or waiver (to the extent permitted by Law) in writing by Rome, at or prior to the Closing, of each of the following additional conditions:

(a) Representations and Warranties. (i) The representations and warranties of the Buyer (other than the representations and warranties of the Buyer set forth in Sections 5.1, 5.2(a) and 5.5) set forth in this Agreement shall be true and correct in all respects as of the Closing Date as though made on and as of such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case the accuracy of such representations and warranties shall be determined as of such date, and without regard to any materiality or Buyer Material Adverse Effect qualifications contained therein), except where the failure of such representations and warranties to be so true and correct would not reasonably be expected to have, individually or in the aggregate, a Buyer Material Adverse Effect, and (ii) the representations and warranties of the Buyer set forth in Sections 5.1, 5.2(a) and 5.5 shall be true and correct (A) in all respects, in the case of any such representations and warranties that are qualified within the text thereof by any materiality or Buyer Material Adverse Effect qualifications, or (B) in all material respects, in the case of any such representations and warranties that are not so qualified within the text thereof by any such materiality or Buyer Material Adverse Effect qualifications, in each case as of the Closing Date as though made on and as of each such date (except to the extent such representations and warranties are specifically made as of a particular date, in which case the accuracy of such representations and warranties shall be determined as of such date).

(b) Performance of Obligations of the Buyer. The Buyer shall have performed or complied in all material respects with all agreements and covenants required to be performed by or complied with by it under this Agreement on or prior to the Closing Date.

(c) Officer's Certificate. The Sellers shall have received a certificate, dated as of the Closing Date and signed on behalf of the Buyer by an executive officer of the Buyer, stating that the conditions specified in Section 8.3(a) and Section 8.3(b) have been satisfied.

ARTICLE IX.
TERMINATION AND AMENDMENT

9.1 Termination. This Agreement may be terminated at any time prior to the Closing (with respect to Sections 9.1(b) through 9.1(e), by written notice by the terminating Party to the other Parties):

(a) by mutual written consent of the Buyer and Rome;

(b) by either the Buyer or Rome if the Acquisition shall not have been consummated by the date that is nine (9) months from the Effective Date (the "End Date"); provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any Party whose breach or failure to perform in any material respect any of its representations, warranties, covenants or agreements under this Agreement has been the primary cause of, or resulted in, the failure of the Acquisition to have been consummated on or before such date;

(c) by either the Buyer or Rome if any Legal Restraint permanently preventing or prohibiting consummation of the Acquisition shall be in effect and shall have become final and non-appealable; provided, however, that the right to terminate this Agreement pursuant to this Section 9.1(c) shall not be available to any Party whose breach or failure to perform in any material respect any of its representations, warranties, covenants or agreements contained in this Agreement has been the primary cause of, or resulted in, such Legal Restraint;

(d) by the Buyer, if there has been a breach of or failure to perform any representation, warranty, covenant or agreement on the part of any Seller or the Company set forth in this Agreement, which breach or failure to perform (i) would cause the conditions set forth in Section 8.2(a) or 8.2(b) not to be satisfied and (ii) if curable, shall not have been cured upon the earlier of (A) 30 days following receipt by Rome of written notice from the Buyer of such breach or failure to perform and (B) the End Date; provided that the Buyer shall not have the right to terminate this Agreement pursuant to this Section 9.1(d) if the Buyer is then in breach in any material respect of any of its respective representations, warranties, covenants or agreements contained in this Agreement, and such breach would give rise to the failure of a condition set forth in Section 8.3(a) or 8.3(b) measured as of such time; or

(e) by Rome, if there has been a breach of or failure to perform any representation, warranty, covenant or agreement on the part of the Buyer set forth in this Agreement, which breach or failure to perform (i) would cause the conditions set forth in Section 8.3(a) or 8.3(b) not to be satisfied and (ii) if curable, shall not have been cured upon the earlier of (A) 30 days following receipt by the Buyer of written notice from Rome of such breach or failure to perform and (B) the End Date; provided that Rome shall not have the right to terminate this Agreement pursuant to this Section 9.1(e) if Rome, Paris or the Company is then in breach in any material respect of any of its respective representations, warranties, covenants or agreements contained in this Agreement, and such breach would give rise to the failure of a condition set forth in Section 8.2(a) or 8.2(b) measured as of such time.

9.2 Effect of Termination. In the event of the valid termination of this Agreement as provided in Section 9.1, this Agreement shall immediately become void and have no effect and there shall be no liability or obligation of any Party; provided, however, that, subject to Section 9.3, (a) any such termination shall not relieve any Party from liability for damages for any Willful Breach of, or Fraud by, such Party prior to such termination, and (b) the provisions of Section 6.3 (Confidentiality), Section 9.3 (Termination Fees), Section 9.4 (Fees and Expenses), Section 9.5 (Amendment), Section 9.6 (Extension; Waiver), this Section 9.2 (Effect of Termination), Article X (Miscellaneous) and Article I (to the extent related to the foregoing) and the Confidentiality Agreement shall remain in full force and effect and survive any termination of this Agreement.

9.3 Termination Fees.

(a) In the event that the Buyer or Rome terminates this Agreement pursuant to Sections 9.1(b) (End Date) or Section 9.1(c) (Legal Restraints) (with respect to Section 9.1(c) (Legal Restraints), solely to the extent the applicable Legal Restraint arises under any Antitrust Law) and, at the time of such termination, (i) the conditions set forth in at least one of Section 8.1(a) (Antitrust Approvals) or Section 8.1(b) (Legal Restraints) (with respect to Section 8.1(b) (Legal Restraints), solely to the extent the failure of such condition to be satisfied arises as a result of a Legal Restraint under any Antitrust Law) shall not have been satisfied or validly waived and the failure of any such condition to be satisfied shall not have been the result of any breach of, or failure to performs its obligations under, this Agreement by any Seller or the Company and (ii) all of the other conditions set forth in Article VIII have been satisfied or validly waived (except for those conditions that by their terms must be satisfied at the Closing, provided that such conditions would have been so satisfied if the Closing would have occurred on the date of termination), then the Buyer shall, upon the written request of the Company (such request to be delivered to the Buyer no later than thirty (30) days following the date of termination of this Agreement) (a "Termination Fee Request"), pay to the Sellers (in accordance with their respective Pro Rata Portions) an aggregate fee equal to $[* * *] (the "Termination Fee"), by wire transfer on the second Business Day following delivery of such request. In the event the Company does not deliver a Termination Fee Request in accordance with the preceding sentence (a "Termination Fee Forfeiture"), (A) each Seller shall be deemed to have irrevocably waived its right to receive its Pro Rata Portion of the Termination Fee and (B) the Company and the Sellers shall be entitled to pursue all other available remedies (subject to Section 9.2). In no event shall the Buyer be required to pay the Termination Fee on more than one occasion.

(b) The Parties acknowledge and agree that the agreements contained in this Section 9.3 are an integral part of the Acquisition, and that, without these agreements, the Parties would not enter into this Agreement; accordingly, if the Buyer fails promptly to pay the Termination Fee when required by Section 9.3(a), and, in order to obtain such payment, any Seller commences a suit that results in a final, non-appealable judgment against the Buyer for such Seller's Pro Rata Portion of the Termination Fee, the Buyer shall pay to the applicable Seller its costs and expenses (including attorneys' fees and expenses) in connection with such suit, in each case, together with interest on such Seller's Pro Rata Portion of the Termination Fee, as applicable, from the date such payment was required to be made until the date of payment at the prime rate set forth in The Wall Street Journal, in effect on the date such payment was required to be made.

(c) In the event the Company delivers a Termination Fee Request and the Termination Fee is paid to the Sellers pursuant to Section 9.3(a), such payment of the Termination Fee shall constitute liquidated damages and be the sole and exclusive monetary remedy of the Sellers and the Company against the Buyer for all losses, damages, costs or expenses in respect of this Agreement (or the termination thereof) or the Acquisition (or the failure of the Acquisition to occur for any reason or for no reason) or any breach of any covenant or agreement or otherwise in respect of this Agreement, and upon payment of the Termination Fee, the Buyer shall not have any further monetary liability or obligation relating to or arising out of this Agreement or the Acquisition, and none of the Sellers or the Company shall seek to recover any other monetary damages; provided, that nothing in this Section 9.3(c) shall be deemed to limit the remedies or damages of the Company or any Seller in the event of a Termination Fee Forfeiture. Each Party further acknowledges that, other than in the case of a Termination Fee Forfeiture, the Termination Fee is not a penalty, but rather is liquidated damages in a reasonable amount that shall compensate the Sellers in the circumstances in which such payment is payable for the efforts and resources expended and opportunities forgone while negotiating this Agreement and in reliance on this Agreement and on the expectation of the consummation of the Acquisition contemplated hereby, which amounts would otherwise be impossible to calculate with precision.

9.4 Fees and Expenses. Except as expressly set forth herein, all fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such fees and expenses, whether or not the Acquisition is consummated.

9.5 Amendment. This Agreement may not be amended or modified except by an instrument in writing making specific reference to this Agreement and signed on behalf of each of the Parties.

9.6 Extension; Waiver. At any time prior to the Closing, a Party may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Parties, (b) waive (with respect solely to such waiving Party) any inaccuracies in the representations and warranties contained herein or in any document delivered pursuant hereto and (c) waive (with respect solely to such waiving Party) compliance with any of the agreements or conditions contained herein. Any agreement on the part of a Party to any such extension or waiver shall be valid only if set forth in a written instrument signed on behalf of such Party making specific reference to this Agreement. Such extension or waiver shall not be deemed to apply to any time for performance, inaccuracy in any representation or warranty, or noncompliance with any agreement or condition, as the case may be, other than that which is specified in the extension or waiver. The failure of any Party to this Agreement to assert any of its rights under this Agreement or otherwise shall not constitute a waiver of such rights.

ARTICLE X.
MISCELLANEOUS

10.1 Notices. All notices and other communications to be given to any Party hereunder shall be sufficiently given for all purposes hereunder if in writing and delivered by hand, courier or overnight delivery service, or by electronic mail ("e-mail") transmission (provided that a "bounceback" or notice of non-receipt by return electronic mail from the recipient is not received) or facsimile transmission, and shall be directed to the address set forth below (or at such other address as such Party shall designate by like notice):

(a) if to the Buyer and, after the Closing, the Company, to:

Roche Holdings, Inc.
1 DNA Way
South San Francisco
California 94080
Attention: General Counsel
Facsimile: [***]

with a copy to (which shall not constitute notice):

F. Hoffman-La Roche Ltd
Grenzacherstrasse 124
CH-4070 Basel
Switzerland
Attention: Group Legal Department
Email: [***]

with a copy to (which shall not constitute notice):

Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017
Attention: Marc O. Williams;
Brian Wolfe
Email: marc.williams@davispolk.com;
brian.wolfe@davispolk.com

(b) if to Rome and, prior to the Closing, the Company, to

Roivant Sciences Ltd.
7th Floor
50 Broadway
London SW1H 0BD
United Kingdom
Attention: Roivant Legal
Email: [***]

with a copy to (which shall not constitute notice):

Freshfields Bruckhaus Deringer US LLP
601 Lexington Avenue, 31st Floor
New York, NY 10022

Attention:	Damien R. Zoubek; Jenny Hochenberg; Adam H. Golden
Email:	damien.zoubek@freshfields.com; jenny.hochenberg@freshfields.com; adam.golden@freshfields.com

10.2 Entire Agreement. This Agreement (including the Company Disclosure Schedule and the Exhibits hereto and other documents and instruments referred to herein that are to be delivered at the Closing) and any other written agreement entered into between or among any of the Parties on the date of this Agreement constitute the entire agreement among the Parties and supersede any prior understandings, agreements or representations by or among the Parties, or any of them, written or oral, with respect to the subject matter hereof; provided, however, that the Confidentiality Agreement shall remain in effect in accordance with its terms.

10.3 No Third-Party Beneficiaries. This Agreement is not intended to, and shall not, confer upon any other Person any rights or remedies hereunder except Sections 2.2(c), 7.9 and 7.11.

10.4 Assignment. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of Law or otherwise by any of the Parties without the prior written consent of each other Party, and any such assignment without such prior written consents shall be null and void, except that the Buyer may transfer or assign its rights and obligations under this Agreement, in whole or from time to time in part, to one or more of its Affiliates; provided, however, that (a) the Buyer shall provide prior written notice of such assignment to the Sellers, (b) such Affiliate shall agree in a writing reasonably satisfactory to the Sellers, for the benefit of the Sellers, to be bound by the terms and conditions of this Agreement, (c) such transfer or assignment shall not relieve the Buyer of its primary liability for its obligations hereunder or enlarge, alter or change any obligation of the Sellers or due to the Buyer and (d) such assignment shall not result in any adverse Tax consequences to any Seller or Company RSU Holder. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

10.5 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.

10.6 Counterparts and Signature. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each of the Parties and delivered to the other Parties, it being understood that the Parties need not sign the same counterpart. This Agreement may be executed and delivered by facsimile or .pdf transmission.

10.7 Interpretation. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) "either" and "or" are not exclusive and "include," "includes" and "including" are not limiting, regardless of the inclusion or exclusion or "without limitation" or words of similar import; (b) "hereof," "hereto," "hereby," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (d) "date hereof" refers to the Effective Date; (e) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if"; (f) descriptive headings, the table of defined terms and the table of contents are inserted for convenience only and do not affect in any way the meaning or interpretation of this Agreement; (g) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (h) references to a person or entity are also to its permitted successors and assigns; (i) references to an "Article," "Section," "Exhibit" or "Schedule" refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement; (j) references to "$" or otherwise to dollar amounts refer to the lawful currency of the United States; (k) references to a Law include any amendment or modification to such Law and any rules, regulations and delegated legislation issued thereunder, whether such amendment or modification is made, or issuance of such rules or regulations occurs, before or, only with respect to events or developments occurring or actions taken or conditions existing after the date of such amendment, modification or issuance, after the Effective Date; (l) references to any Governmental Authority include any successor Governmental Authority thereto; (m) references to a communication by a regulatory agency include a communication by the staff of such regulatory agency; (n) "made available to," "delivered" and phrases of similar import mean, with respect to any information, document or other material, that such information, document or material was made available for review at least two days prior to 12 pm on the Effective Date in the virtual data room entitled "Vision" at datasite.com and created for purposes of the Acquisition and (o) any Contract or instrument defined or referred to herein means such Contract or instrument as from time to time amended, modified or supplemented, whether or not so specified. In the event that any Seller converts any shares of such Seller's Preferred Stock into Common Stock in accordance with the Company's Constitutive Documents, any references to the Company Shares in this Agreement shall be deemed to refer to the shares of Common Stock issued upon such conversion in lieu of such shares of Preferred Stock that have been so converted, *mutatis mutandis*. In the event that any Seller transfers any shares of such Seller's Company Shares to a transferee in accordance with Section 3.1 of the ROFR and Co-Sale Agreement, any references to such Seller in this Agreement shall be deemed to refer to such transferee with respect to such Company Shares and such transfer shall be subject to such transferee agreeing in writing (in a form and substance reasonably acceptable to Buyer) for the benefit of the Buyer to be bound by the terms and conditions of this Agreement as the applicable transferring Seller hereunder with respect to all of such Company Shares. The language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Party. No summary of this Agreement prepared by any Party shall affect the meaning or interpretation of this Agreement.

10.8 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal Laws of the State of Delaware, including its statutes of limitations, without regard to any borrowing statute that would result in the application of the statute of limitations of any other jurisdiction.

10.9 Remedies. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by Law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy. The Parties agree that irreparable harm would occur if any of the provisions of this Agreement were not performed in accordance with their specific terms on a timely basis or were otherwise breached. It is accordingly agreed that without posting bond or other undertaking, the Parties shall be entitled to injunctive or other equitable relief to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of competent jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. The Parties further agree that (a) by seeking any remedy provided for in this Section 10.9, a Party shall not in any respect waive its right to seek any other form of relief that may be available to such Party under this Agreement and (b) nothing contained in this Section 10.9 shall require any Party to institute any Action for (or limit such Party's right to institute any Action for) specific performance under this Section 10.9 before exercising any other right under this Agreement. Each of the Parties agrees that it will not oppose, and irrevocably waives its right to object to, the granting of an injunction, specific performance or other equitable relief on the basis that another Party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity.

10.10 Submission to Jurisdiction. With respect to any Action resulting from, concerning, relating to or arising out of this Agreement, each of the Parties irrevocably and unconditionally consents and submits to the sole and exclusive jurisdiction of the Court of Chancery of the State of Delaware or, if such court shall not accept jurisdiction, the United States District Court for the District of Delaware, and any appellate court from any thereof. In any such Action resulting from, concerning, relating to or arising out of this Agreement, each of the Parties irrevocably and unconditionally waives and agrees not to assert by way of motion, as a defense or otherwise (a) any claim that it is not subject to the jurisdiction of the above courts, (b) that its property is exempt or immune from attachment or execution in any such Action in the above-named courts, (c) that such Action is brought in an inconvenient forum, (d) that the venue of such Action is improper or (e) that such Action should be transferred or removed to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such courts. Each of the Parties hereby agrees not to commence any such Action other than before one of the above-named courts. Each of the Parties also hereby agrees that any final and unappealable judgment against a Party in connection with any such Action shall be conclusive and binding on such Party and that such judgment may be enforced in any court of competent jurisdiction, either within or outside of the United States. A certified or exemplified copy of such award or judgment shall be conclusive evidence of the fact and amount of such award or judgment. With respect to any Action for which it has submitted to jurisdiction pursuant to this Section 10.10, each Party irrevocably consents to service of process in the manner provided for the giving of notices pursuant to Section 10.1, with the same legal force and effect as if served upon such Party personally within the State of Delaware. Nothing in this Section 10.10 shall affect the right of any Party to serve process in any other manner permitted by Law.

10.11 WAIVER OF JURY TRIAL. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER, RELATED TO OR IN CONNECTION WITH THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY FOR ANY DISPUTE ARISING OUT OF, RELATED TO OR IN CONNECTION WITH THIS AGREEMENT OR THE BREACH, TERMINATION OR VALIDITY THEREOF OR ANY TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (A) NEITHER THE OTHER PARTIES NOR THEIR REPRESENTATIVES, AGENTS OR ATTORNEYS HAVE REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTIES WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) EACH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER AND HAS HAD AN OPPORTUNITY TO CONSULT WITH COUNSEL CONCERNING THIS WAIVER, (C) EACH PARTY MAKES THIS WAIVER VOLUNTARILY AND (D) EACH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS OF THIS SECTION 10.11. ANY PARTY MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

10.12 Company Disclosure Schedule. The Company Disclosure Schedule shall be arranged in Sections corresponding to the numbered Sections contained in Article III or Article IV, as the case may be, and the disclosure in any Section shall qualify (a) the corresponding Section in Article III or Article IV, as the case may be, and (b) the other Sections in Article III or Article IV, as the case may be, to the extent that it is reasonably apparent from the content and context of such disclosure that it also qualifies or applies to such other Sections. The inclusion of any information in the Company Disclosure Schedule shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in a Seller Material Adverse Effect or Business Material Adverse Effect, or is outside the Ordinary Course.

10.13 Non-Survival of Representations, Warranties and Covenants. The representations, warranties, covenants and agreements set forth in this Agreement or in any certificate delivered pursuant to this Agreement shall terminate at, and will not survive, the Closing, except with respect to (a) Fraud in respect of any representation and warranty set forth is this Agreement, in which case the applicable representation or warranty shall survive Closing, solely with respect to such Fraud and solely until any claim related thereto is finally resolved, (b) those covenants and agreements of the Parties contained in this Agreement that by their terms contemplate performance at or after the Closing, which shall survive the Closing in accordance with their respective terms, (c) this Article X (and any corresponding definitions set forth in Article I or elsewhere in this Agreement) and (d) for the avoidance of doubt, the acknowledgements and agreements set forth in Sections 3.5, 3.6, 4.27, 4.28, 5.7 and 5.8 shall survive indefinitely.

10.14 Joint Negotiation. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises under any provision of this Agreement, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement. The Parties each hereby acknowledge that this Agreement reflects an agreement between sophisticated Parties derived from arm's-length negotiations. Further, prior drafts of this Agreement or the fact that any clauses have been added, deleted or otherwise modified from any prior drafts of this Agreement shall not be used as an aide of construction or otherwise constitute evidence of the intent of the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of such prior drafts.

10.15 Waiver of Conflicts; Privilege.

(a) The Buyer acknowledges and agrees that Freshfields Bruckhaus Deringer US LLP ("Freshfields") has acted as counsel to the Company and Rome in connection with this Agreement and the transactions contemplated hereby.

(b) The Buyer hereby consents and agrees to, and agrees to cause the Company Group to consent and agree to, Freshfields representing Rome and its Affiliates (collectively, the "Rome Parties") after the Closing with respect to disputes in which the interests of the Rome Parties may be directly adverse to the Buyer and its Subsidiaries (including, after the Closing, the Company Group). The Buyer further consents and agrees to, and agrees to cause the Company Group to consent and agree to, the communication by Freshfields to the Rome Parties in connection with any such representation of any fact known to Freshfields arising by reason of Freshfields's prior representation of the Company in connection with this Agreement and consummation of the transactions contemplated hereby.

(c) In connection with the foregoing, the Buyer hereby irrevocably waives and agrees not to assert, and agrees to cause the Company Group to irrevocably waive and not to assert, any conflict of interest arising from or in connection with (i) Freshfields's prior representation of the Company in connection with this Agreement and consummation of the transactions contemplated hereby and (ii) Freshfields's representation of the Rome Parties prior to and after the Closing.

(d) The Buyer further agrees, on behalf of itself and, after the Closing, on behalf of the Company Group, that all communications in any form or format whatsoever between or among any of Freshfields, the Company Group and/or any Rome Party, or any of their respective Representatives that relate in any way to the negotiation, documentation and consummation of the transactions contemplated by this Agreement or any dispute arising under this Agreement (collectively, the "Deal Communications") shall be deemed to be retained and owned collectively by the Rome Parties, shall be controlled by Rome on behalf of the Rome Parties and shall not pass to or be claimed by the Buyer or the Company Group. All Deal Communications that are attorney-client privileged (the "Privileged Deal Communications") shall remain privileged after the Closing and the privilege and the expectation of client confidence relating thereto shall belong solely to the Rome Parties, shall be controlled by Rome on behalf of the Rome Parties and shall not pass to or be claimed by the Buyer or the Company Group.

(e) Notwithstanding the foregoing, in the event that a dispute arises between the Buyer or any member of the Company Group, on the one hand, and a Third Party other than a Rome Party, on the other hand, the Buyer or such member of the Company Group may assert the attorney-client privilege to prevent the disclosure of the Privileged Deal Communications to such Third Party; provided, however, that none of the Buyer or any member of the Company Group may waive such privilege without the prior written consent of Rome.

(f) To the extent that files or other materials maintained by Freshfields constitute property of its clients, only the Rome Parties shall hold such property rights and Freshfields shall have no duty to reveal or disclose any such files or other materials or any Deal Communications by reason of any attorney-client relationship between Freshfields, on the one hand, and the Company, on the other hand.

(g) The Buyer agrees that it shall not, and that following the Closing it shall cause the Company Group not to, access or use the Deal Communications, including by way of review of any electronic data, communications or other information, by seeking to have any Rome Party waive the attorney-client or other privilege, or by otherwise asserting that the Buyer or the Company has the right to waive the attorney-client or other privilege.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the Buyer, the Company and the Sellers have caused this Agreement to be signed by their respective officers thereunto duly authorized as of the date first written above.

ROCHE HOLDINGS, INC.

By: /s/ Bruce Resnick
Name: Bruce Resnick
Title: Vice President

ROIVANT SCIENCES LTD.

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

TELAVANT HOLDINGS, INC.

By: /s/ Frank Torti
Name: Frank Torti
Title: Director

EXHIBIT C

JOINDER AGREEMENT

THIS JOINDER AGREEMENT (this "Joinder") to that certain Stock Purchase Agreement dated as of October 22, 2023 (as it may be amended, supplemented or otherwise modified, the "Agreement"), by and among **Roche Holdings, Inc.**, a Delaware corporation (the "Buyer"), **Roivant Sciences Ltd.**, an exempted company limited by shares incorporated under the laws of Bermuda ("Rome"), and **Telavant Holdings, Inc.**, a Delaware corporation (the "Company"), is made and entered into as of October 22, 2023 by Rome and **Pfizer Inc.**, a Delaware corporation ("Paris") (collectively with Rome, the "Sellers"). Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

WHEREAS, (a) Rome is the beneficial owner and holder of record of 70,000,000 shares of Common Stock and 35,000,000 shares of Series A-1 Preferred Stock (collectively, the "Rome Company Shares") and (b) Paris is the beneficial owner and holder of record of 35,000,000 shares of Series A-2 Preferred Stock (the "Paris Company Shares" and, together with the Rome Company Shares, the "Company Shares");

WHEREAS, the Agreement provides for the purchase by the Buyer from the Sellers, and the sale by the Sellers to the Buyer, of all of the Company Shares upon the terms and subject to the conditions of the Agreement (such purchase and sale, together with all other transactions contemplated by the Agreement, the "Acquisition");

WHEREAS, the Acquisition implies a valuation of the Company of at least $400,000,000 and constitutes a "Solitary Drag Along Sale" under and for purposes of the Right of First Refusal and Co-Sale Agreement, dated as of November 21, 2022, by and among the Company, Rome and Paris (the "ROFR & Co-Sale Agreement"); and

WHEREAS, Rome has requested that Paris participate in the Acquisition as set forth in Section 2.3 (Drag Along Rights) of the ROFR & Co-Sale Agreement on the terms and conditions set forth in this Joinder and the Agreement, and has delivered to Paris the Drag-Along Sale Notice referred to in Section 2.3(d) of the ROFR & Co-Sale Agreement.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Rome and Paris agree as follows:

1. Paris hereby accedes to the Agreement as "Paris" and a "Seller" thereunder and agrees to be subject to, and bound by, all terms and provisions of the Agreement specifically applicable to "Paris" or a "Seller" thereunder and to have all the rights and obligations of "Paris" and the "Sellers" (or any and each "Seller") thereunder and as provided therein, in each case with the same force and effect as if it had executed and delivered the Agreement as of the Effective Date;

2. In addition to the foregoing, Paris hereby acknowledges and accepts the provisions of Section 2.5 (Actions in Connection with the Closing), Article III (Seller Representations and Warranties) (other than Section 3.4), Section 7.2(a), Section 7.2(d) and Section 7.2(e) (Consents and Regulatory Approvals), Section 7.4 (Public Disclosure), Section 9.2 (Effect of Termination), Section 9.3 (Termination Fees), Section 9.4 (Fees and Expenses), Section 10.2 (Entire Agreement), Section 10.5 (Severability), Section 10.7 (Interpretation), Section 10.8 (Governing Law), Section 10.9 (Remedies), Section 10.10 (Submission to Jurisdiction), Section 10.11 (Waiver of Jury Trial), Section 10.13 (Non-Survival or Representations, Warranties and Covenants) and Section 10.14 (Joint Negotiation) (other than the first sentence thereof) and any references therein to the "Parties" or a "Party" shall be deemed to include Paris. For the avoidance of doubt, Paris shall not be deemed to be a "Party" to the Agreement for purposes of any other provisions, except (a) those Sections set forth above in this paragraph 2 and (b) those provisions specifically applicable to "Paris" or the "Sellers" (or any or each "Seller") as set forth in paragraph 1 above.

3. Paris hereby (a) makes all of the representations and warranties set forth in Article III of the Agreement (other than the representations and warranties set forth in Section 3.4 of the Agreement) and (b) agrees to deliver the certificate required to be delivered pursuant to Section 8.2(c)(ii) of the Agreement on, or prior to, the Closing Date.

4. Rome and Paris hereby agree that effective as of immediately following the Closing, each of the Paris Transaction Agreements and the Stock Purchase Agreement, dated November 21, 2022, by and among Rome, Paris and the Company (collectively, the "Terminated Paris Agreements") shall automatically terminate and Rome shall have no further (and shall be irrevocably and unconditionally released and discharged from any and all) obligations or liabilities thereunder, and the Terminated Paris Agreements shall be of no further force and effect.

5. Paris hereby agrees that it shall execute and deliver such instruments of conveyance and transfer and take such other action, including executing any agreement with respect to the Acquisition, as may be reasonably required at the request of Rome in order to carry out the terms and provisions of Section 2.3 of the ROFR & Co-Sale Agreement and consummate the Acquisition.

6. Rome hereby agrees that this Joinder shall automatically terminate and become void in the event that the Agreement is (x) amended or otherwise modified, without the prior written consent of Paris, in a manner such that the Acquisition would no longer constitute a "Solitary Drag Along Sale" under the ROFR & Co-Sale Agreement or otherwise in a manner such that the requirements of Section 2.3(b) or Section 2.3(f) of ROFR & Co-Sale Agreement would cease to be satisfied with respect to the Acquisition (it being acknowledged by Paris that the Agreement and the terms and conditions of the Acquisition, as in effect on the date hereof, comply with all requirements of Section 2.3 of the ROFR & Co-Sale Agreement and Rome is entitled to its drag-along rights specified therein with respect thereto); provided, however, that, for the avoidance of doubt, except as expressly set forth in this paragraph 6, nothing in this Joinder shall be deemed to prevent or otherwise restrict (or grant Paris a consent right with respect to) any amendments, waivers or other modifications to the Agreement as may be agreed between Rome, the Company and the Buyer or (y) terminated in accordance with its terms.

7. All notices and other communications to be given to Paris in connection with the Agreement shall be sufficiently given for all purposes hereunder if in writing and delivered by hand, courier or overnight delivery service, or by electronic mail ("e-mail") transmission (provided that a "bounceback" or notice of non-receipt by return electronic mail from the recipient is not received), and shall be directed to the address set forth below (or at such other address as Paris shall designate by like notice):

Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001-2192
Attention: General Counsel
Email: [***]

with a copy to (which shall not constitute notice):

Arnold & Porter Kaye Scholer LLP
250 West 55th Street
New York, NY 10019
Attention: Lowell Dashefsky, David Menchel
Email: Lowell.Dashefksy@arnoldporter.com,
David.Menchel@arnoldporter.com

8. This Joinder and the Agreement (including the Company Disclosure Schedule and the Exhibits thereto and other documents and instruments referred to therein that are to be delivered at the Closing) constitutes the entire agreement among between Rome, Paris and the Buyer and supersedes any prior understandings, agreements or representations by or among Rome, Paris and the Buyer, or any of them, written or oral, with respect to the subject matter hereof.

9. The Buyer shall be an express third-party beneficiary of this Joinder, with the right to enforce the terms and conditions of this Joinder.

10. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party hereto shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by Law or equity upon such party, and the exercise by a party hereto of any one remedy shall not preclude the exercise of any other remedy. The parties hereto agree that irreparable harm would occur if any of the provisions of this Joinder were not performed in accordance with their specific terms on a timely basis or were otherwise breached. It is accordingly agreed that without posting bond or other undertaking, the parties hereto shall be entitled to injunctive or other equitable relief to prevent breaches or threatened breaches of this Joinder and to enforce specifically the terms and provisions of this Joinder in any court of competent jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. The parties hereto further agree that (a) by seeking any remedy provided for in this paragraph 10, a party shall not in any respect waive its right to seek any other form of relief that may be available to such party under this Joinder and (b) nothing contained in this paragraph 10 shall require any party hereto to institute any Action for (or limit such party's right to institute any Action for) specific performance under this paragraph 10 before exercising any other right under this Joinder. Each of the parties hereto agrees that it will not oppose, and irrevocably waives its right to object to, the granting of an injunction, specific performance or other equitable relief on the basis that another party has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity.

11. The following provisions from the Agreement shall be deemed incorporated into this Joinder as if set forth herein, *mutatis mutandis*: Section 10.4 (Assignment), Section 10.5 (Severability), Section 10.6 (Counterparts and Signature), Section 10.7 (Interpretation), Section 10.8 (Governing Law), Section 10.10 (Submission to Jurisdiction) and Section 10.11 (WAIVER OF JURY TRIAL).

12. This Joinder may not be amended or modified without the prior written consent of the Buyer. Additionally, neither this Joinder nor any of the rights, interests or obligations under this Joinder may be assigned or delegated, in whole or in part, by operation of Law or otherwise, by either Rome or Paris without the prior written consent of the Buyer, and any such assignment without such prior written consent shall be null and void.

[*Signature Page Follows*.]

IN WITNESS WHEREOF, Paris and Rome have caused this Joinder to be signed by their respective officers thereunto duly authorized as of the date first written above.

PFIZER INC.

By: _____
Name:
Title:

ROIVANT SCIENCES LTD.

By: _____
Name:
Title:

[*Signature Page to Stock Purchase Agreement*]

EXHIBIT G

Milestone Payment

Capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

1. Milestones.

(a) Subject to the remainder of this Exhibit G, if the Closing shall have occurred, upon the first occurrence of the milestone event described in the table set forth below by the Buyer or any Buyer Party with respect to any Milestone Product (the "Milestone Event"), the Buyer shall pay or cause to be paid cash in an amount equal to the milestone payment listed next to such Milestone Event below (the "Milestone Payment") in accordance with Section 2 of this Exhibit G and Section 2.7 of the Agreement. The Milestone Event and corresponding Milestone Payment is as follows:

Milestone Event	Milestone Payment
Initiation of a Phase 3 Clinical Trial of a Milestone Product in the UC Indication [***].	$150,000,000

(b) Notwithstanding anything to the contrary in the Agreement or this Exhibit G, (i) the maximum aggregate amount the Buyer and any other Buyer Party shall be obligated to pay pursuant to this Exhibit G shall be $150,000,000, (ii) the Milestone Event may not be achieved more than one time, (iii) no more than one Milestone Payment shall be payable with respect to the Milestone Event and (iv) the Milestone Payment for the Milestone Event shall not be payable more than one time (regardless of (A) the number of additional times the Milestone Event is achieved and (B) the number of subsequent Milestone Products achieving the Milestone Event). Buyer and each Seller acknowledges and agrees that it is possible that, without any breach of the Agreement, this Exhibit G or any other document entered into with respect to the transactions contemplated by the Agreement by the Buyer or any of the Buyer Parties, the Milestone Event may not be timely achieved, in which case the Milestone Payment will not be made.

2. Notice and Payment.

(a) The Milestone Payment to be made by or on behalf of the Buyer pursuant to this Exhibit G and the Agreement shall be made in U.S. dollars and shall be paid by wire transfer of immediately available funds in accordance with Section 2.7 of the Agreement.

(b) No later than ten (10) Business Days after the occurrence of the Milestone Event, the Buyer shall provide written notice to each Seller of the occurrence of the Milestone Event. Promptly upon receipt of such notice, Rome shall issue a payment request to the Buyer on behalf of the Sellers and the Company RSU Holders for the Buyer to make payment of the corresponding Milestone Payment in accordance with Section 2.7 of the Agreement, and the Buyer shall make such payment within [***] of receipt of such request.

3. Diligence Obligations. From and after the Closing, the Buyer Parties shall have the right, in their sole and absolute discretion, to direct and control the use, research, Development, Manufacture and Commercialization of all Milestone Products in all respects, including the determination to test, Develop, pursue, market, make any Regulatory Filings with respect to, or make any strategic decisions affecting, such Milestone Products. [***].

4. **Divestitures.** If at any time after the Closing [***], the Buyer or the Company Group divests or transfers (by way of merger, consolidation, asset acquisition or sale, exclusive license, exclusive sublicense, sale, assignment or other similar transfer) (a "Divestiture") to a Third Party all or substantially all of the Buyer's or the Company Group's right, title and interest in and to any Milestone Product and the Intellectual Property assets related to the same (collectively, "Divested Assets" and the party receiving any Divested Assets the "Transferee"), the Buyer will: (a) make provision for the Transferee to assume and succeed to the obligations of the Buyer set forth in this Exhibit G and any related payment obligations under the Agreement with respect to the Milestone Event; and (b) prior to or simultaneously with the consummation of any such Divestiture, cause such Transferee to provide to Rome an instrument of assumption in a form reasonably acceptable to Rome, for the benefit of the Sellers, effecting the assumption and succession described in the foregoing clause (a).

5. **Definitions.** For the purposes of this Exhibit G:

"Buyer Parties" means the Buyer and its Affiliates (including after the Closing, the Company Group), and, with respect to any Milestone Products, any of their successors, permitted assigns, licensees, sublicensees, contractors or subcontractors.

"Commercially Reasonable Efforts" means, with respect to any obligation for any Milestone Product, [***].

"Indication" means a disease or medical condition for which a Milestone Product is directed with the aim of receiving Regulatory Approval for the treatment of such disease or medical condition with such Milestone Product.

"Initiation" means, with respect to a Clinical Trial for any Indication, [***]. "Initiate" has a correlative meaning.

"Milestone Product" means a Program Product containing or comprising the TL1A Monoclonal Antibody RVT-3101 developed by any Buyer Party whether as a monotherapy or a combination product/therapy, and regardless of finished form, formulation or dosage, whereby the composition of matter of such TL1A Monoclonal Antibody is Covered by at least one Valid Claim.

"UC Indication" means ulcerative colitis.

"Valid Claim" means a claim of any issued and unexpired United States Patent included in the Company Owned Intellectual Property or Company Exclusively Licensed Intellectual Property as of the Closing that has not been held to be permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction in a final decision that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid, unenforceable or unpatentable, including through reissue, re-examination or disclaimer or otherwise.

* * * * *

Exhibit 31.1

CERTIFICATION

I, Matthew Gline, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Roivant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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: November 13, 2023

/s/ Matthew Gline
Matthew Gline
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Richard Pulik, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Roivant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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: November 13, 2023

/s/ Richard Pulik
Richard Pulik
Principal Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Matthew Gline, Principal Executive Officer of Roivant Sciences Ltd. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, 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: November 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.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Richard Pulik, Principal Financial Officer of Roivant Sciences Ltd. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, 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: November 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.