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, 2024
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 Select 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 8, 2024, the registrant had 727,949,744 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 account on the social media platform X (formerly Twitter) (@Roivant), other social media platforms, webcasts, press releases and conference calls. Similarly, Immunovant, Inc., as well as our other subsidiaries, 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 subsidiaries use these mediums to communicate with our and our 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 subsidiaries to review this information.

The above-referenced information is not incorporated by reference into this filing and the website addresses and X 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 1A. 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 and affiliates, as the context requires. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

Risks Related to Our Business and Industry

- Our relatively limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development and commercialization may make it difficult for us to execute on our business model and for you to assess our future viability.
- We may never achieve sustained profitability.
- We may not be successful in our efforts to acquire or in-license new product candidates, and newly acquired or in-licensed product candidates may not perform as expected in clinical trials or be successful in eventually achieving marketing approvals.
- 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 product candidates.
- We face risks associated with strategic transactions and partnerships and we may not realize the expected benefits of those strategic transactions and partnerships.
- We face risks associated with the use of our cash, cash equivalents and marketable securities, including any return of capital to shareholders.
- Clinical trials and preclinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or preclinical studies on the expected timelines, if at all.
- We may encounter difficulties enrolling and retaining patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.
- The results of our preclinical studies and clinical trials may not support our proposed claims for our 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 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 product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

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

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

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

- The length of our patent terms may be inadequate to protect the competitive position of our product candidates for an adequate amount of time.

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

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

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

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

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

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

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

Forward-Looking Statements

This 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 relatively limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development and commercialization;
- our ability to acquire or in-license new product candidates;
- the allocation of capital and personnel across our business;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- potential future payments related to our product candidates;
- our ability to consummate and realize the benefits from strategic transactions and partnerships, including the Dermavant Transaction;
- the use of our cash, cash equivalents and marketable securities;
- 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 product candidates, including any manufacturing problems that result in delays in development or commercialization of our product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials, which could adversely affect or otherwise delay clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- interim, top-line or preliminary data from our clinical trials changing as more data become available or data being delayed due to audit or verification processes;
- changes in product candidate 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 or to otherwise perform in a satisfactory manner or to comply with applicable legal, regulatory or other requirements;
- the fact that obtaining approvals for new drugs is an extensive, lengthy, expensive and inherently uncertain process that may end with our inability to obtain regulatory approval by the FDA or other regulatory agencies in other jurisdictions;
- the failure of our clinical trials to demonstrate substantial evidence of the safety and efficacy of our product candidates;

- our inability to obtain regulatory approval for a product candidate in certain jurisdictions, even if we are able to obtain approval in certain other jurisdictions;
- our ability to effectively manage growth and to attract and retain key personnel;
- any business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally;
- our ability to obtain and maintain patent and other intellectual property protection for our technology, product candidates;
- the inadequacy of patent terms and their scope to protect our competitive position;
- the failure to issue (or the threatening of their breadth or strength of protection) or provide meaningful exclusivity for our product candidates of our patent applications that we hold or have in-licensed;
- 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 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. References to our “product candidates” include our current and any future products or product candidates. 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 forward-looking 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, 2024	March 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,958,633	$ 6,494,953
Marketable securities	3,428,021	—
Other current assets	94,226	80,605
Current assets of discontinued operations (Note 6)	320,239	156,270
Total current assets	5,801,119	6,731,828
Property and equipment, net	13,674	15,322
Operating lease right-of-use assets	42,977	44,002
Investments measured at fair value	311,354	247,753
Other assets	36,904	37,701
Noncurrent assets of discontinued operations (Note 6)	—	145,876
Total assets	$ 6,206,028	$ 7,222,482
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 25,127	$ 14,029
Accrued expenses	111,469	119,417
Operating lease liabilities	9,519	8,966
Other current liabilities	8,921	13,941
Current liabilities of discontinued operations (Note 6)	401,213	110,405
Total current liabilities	556,249	266,758
Liability instruments measured at fair value	26,252	25,737
Operating lease liabilities, noncurrent	43,190	45,020
Other liabilities	295	2,493
Noncurrent liabilities of discontinued operations (Note 6)	—	433,945
Total liabilities	625,986	773,953
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 733,328,375 and 806,677,954 shares issued and outstanding at September 30, 2024 and March 31, 2024, respectively	—	—
Additional paid-in capital	4,775,411	5,396,492
Retained earnings	395,580	576,172
Accumulated other comprehensive loss	(18,036)	(4,083)
Shareholders' equity attributable to Roivant Sciences Ltd.	5,152,955	5,968,581
Noncontrolling interests	427,087	479,948
Total shareholders' equity	5,580,042	6,448,529
Total liabilities and shareholders' equity	$ 6,206,028	$ 7,222,482

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,	
	2024	2023	2024	2023
Revenue, net	$ 4,475	$ 3,648	$ 12,465	$ 8,131
Operating expenses:				
Cost of revenues	234	223	447	1,206
Research and development (includes $9,911 and $8,309 of share-based compensation expense for the three months ended September 30, 2024 and 2023 and $20,443 and $15,726 for the six months ended September 30, 2024 and 2023, respectively)	143,073	114,790	263,580	224,206
Acquired in-process research and development	—	13,950	—	26,450
General and administrative (includes $59,443 and $37,755 of share-based compensation expense for the three months ended September 30, 2024 and 2023 and $96,284 and $76,472 for the six months ended September 30, 2024 and 2023, respectively)	202,881	88,576	302,773	179,858
Total operating expenses	346,188	217,539	566,800	431,720
Gain on sale of Telavant net assets	—	—	110,387	—
Loss from operations	(341,713)	(213,891)	(443,948)	(423,589)
Change in fair value of investments	(48,375)	45,849	(63,601)	53,413
Change in fair value of liability instruments	(635)	11,789	515	51,967
Gain on deconsolidation of subsidiaries	—	(17,354)	—	(17,354)
Interest income	(69,773)	(14,299)	(141,900)	(31,014)
Other expense, net	1,453	1,530	5,061	4,357
Loss from continuing operations before income taxes	(224,383)	(241,406)	(244,023)	(484,958)
Income tax expense	12,458	3,236	24,421	4,911
Loss from continuing operations, net of tax	(236,841)	(244,642)	(268,444)	(489,869)
(Loss) income from discontinued operations, net of tax	(43,083)	(86,476)	46,010	(169,094)
Net loss	(279,924)	(331,118)	(222,434)	(658,963)
Net loss attributable to noncontrolling interests	(49,740)	(26,791)	(87,547)	(62,820)
Net loss attributable to Roivant Sciences Ltd.	$ (230,184)	$ (304,327)	$ (134,887)	$ (596,143)
Amounts attributable to Roivant Sciences Ltd.:				
Loss from continuing operations, net of tax	$ (187,101)	$ (218,226)	$ (181,052)	$ (427,784)
(Loss) income from discontinued operations, net of tax	(43,083)	(86,101)	46,165	(168,359)
Net loss attributable to Roivant Sciences Ltd.	$ (230,184)	$ (304,327)	$ (134,887)	$ (596,143)
Basic and diluted net (loss) income per common share:				
Basic and diluted loss from continuing operations	$ (0.25)	$ (0.28)	$ (0.25)	$ (0.56)
Basic and diluted (loss) income from discontinued operations	$ (0.06)	$ (0.11)	$ 0.06	$ (0.22)
Basic and diluted net loss per common share	$ (0.31)	$ (0.40)	$ (0.18)	$ (0.78)
Weighted average shares outstanding:				
Basic	735,470,796	770,227,849	735,642,721	764,780,630
Diluted	735,470,796	770,227,849	735,642,721	764,780,630

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,	
	2024	2023	2024	2023
Net loss	$ (279,924)	$ (331,118)	$ (222,434)	$ (658,963)
Other comprehensive income (loss):				
Change in fair value of debt due to change in subsidiary credit risk	7,100	—	(3,500)	—
Foreign currency translation adjustment	(6,894)	3,602	(10,126)	(546)
Total other comprehensive income (loss)	206	3,602	(13,626)	(546)
Comprehensive loss	(279,718)	(327,516)	(236,060)	(659,509)
Comprehensive loss attributable to noncontrolling interests	(49,446)	(26,727)	(87,220)	(62,911)
Comprehensive loss attributable to Roivant Sciences Ltd.	$ (230,272)	$ (300,789)	$ (148,840)	$ (596,598)

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

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

	Shareholders' Equity						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Noncontrolling Interests	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2024	**806,677,954**	**$ —**	**$ 5,396,492**	**$ (4,083)**	**$ 576,172**	**$ 479,948**	**$ 6,448,529**
Issuance of the Company's common shares in connection with equity incentive plans and tax withholding payments	3,626,235	—	(11,147)	—	—	—	(11,147)
Issuance of subsidiary common shares, net	—	—	11,647	—	—	—	11,647
Subsidiary stock options exercised	—	—	433	—	—	312	745
Cash contributions to majority-owned subsidiaries	—	—	(69)	—	—	69	—
Repurchase of common shares	(71,251,083)	—	(648,385)	—	—	—	(648,385)
Share-based compensation	—	—	32,817	—	—	17,422	50,239
Change in fair value of debt due to change in subsidiary credit risk	—	—	—	(10,600)	—	—	(10,600)
Foreign currency translation adjustment	—	—	—	(3,265)	—	33	(3,232)
Net income (loss)	—	—	—	—	95,297	(37,807)	57,490
Balance at June 30, 2024	**739,053,106**	**$ —**	**$ 4,781,788**	**$ (17,948)**	**$ 671,469**	**$ 459,977**	**$ 5,895,286**
Issuance of the Company's common shares in connection with equity incentive plans, net of forfeitures, and tax withholding payments	3,226,784	—	(2,597)	—	—	—	(2,597)
Subsidiary stock options exercised	—	—	430	—	—	332	762
Issuance of the Company's common shares under employee stock purchase plan	72,143	—	648	—	—	—	648
Cash contributions to majority-owned subsidiaries	—	—	(119)	—	—	119	—
Repurchase of common shares	(9,023,658)	—	(60,349)	—	(45,705)	—	(106,054)
Share-based compensation	—	—	55,610	—	—	16,105	71,715
Change in fair value of debt due to change in subsidiary credit risk	—	—	—	7,100	—	—	7,100
Foreign currency translation adjustment	—	—	—	(7,188)	—	294	(6,894)
Net loss	—	—	—	—	(230,184)	(49,740)	(279,924)
Balance at September 30, 2024	**733,328,375**	**$ —**	**$ 4,775,411**	**$ (18,036)**	**$ 395,580**	**$ 427,087**	**$ 5,580,042**

	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**

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (222,434)	$ (658,963)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	121,860	98,578
Change in fair value of investments	(63,601)	53,413
Change in fair value of debt and liability instruments	(102,137)	76,045
Gain on deconsolidation of subsidiaries	—	(17,354)
Gain on sale of Telavant net assets	(110,387)	—
Accretion of discount and amortization of premium on marketable securities, net	(25,036)	—
Depreciation and amortization	9,725	11,426
Non-cash lease expense	3,160	3,316
Other	(12,360)	5,295
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Other current assets	(12,206)	(26,279)
Accounts payable	(18,057)	10,142
Accrued expenses	(16,474)	(12,390)
Operating lease liabilities	(3,444)	(4,154)
Other	(8,244)	14,566
Net cash used in operating activities	(459,635)	(446,359)
Cash flows from investing activities:		
Purchase of marketable securities	(3,402,985)	—
Purchase of property and equipment	(1,961)	(678)
Proceeds from sale of subsidiary interests	110,387	47,500
Cash decrease upon deconsolidation of subsidiaries	—	(83,679)
Other	—	511
Net cash used in investing activities	(3,294,559)	(36,346)
Cash flows from financing activities:		
Proceeds from issuance of the Company's common shares, net of issuance costs paid	—	199,822
Payment of subsidiary dividend	—	(6,000)
Repayment of debt by subsidiary	(3,000)	(14,471)
Payments on principal portion of finance lease obligations	(662)	(907)
Proceeds from exercise of the Company's and subsidiary stock options	8,891	42,142
Taxes paid related to net settlement of equity awards	(21,128)	(5,788)
Repurchase of common shares	(754,439)	—
Proceeds from issuance of the Company's common shares under employee stock purchase plan	648	587
Proceeds from exercise of the Company's warrants	—	5
Payment for redemptions of the Company's warrants	—	(41)
Net cash (used in) provided by financing activities	(769,690)	215,349
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	2,303	(1,571)
Net change in cash, cash equivalents and restricted cash	(4,521,581)	(268,927)
Cash, cash equivalents and restricted cash at beginning of period	6,550,450	1,692,115
Cash, cash equivalents and restricted cash at end of period	$ 2,028,869	$ 1,423,188
Non-cash investing and financing activities:		
Cashless exercise of the Company's warrants	$ —	$ 83,258
Issuance of subsidiary shares in connection with Debt Renegotiation	$ 11,647	$ —
Other	$ 1,869	$ 33

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

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

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

(B) Liquidity

Historically, the Company has incurred significant operating losses and negative cash flows from operations since its inception. In December 2023, the Company sold its entire equity interest in its majority-owned subsidiary Telavant Holdings, Inc. ("Telavant"). At closing, the Company received approximately $5.2 billion in cash. As of September 30, 2024, the Company had cash, cash equivalents, and marketable securities of approximately $5.4 billion and its retained earnings was $395.6 million. For the six months ended September 30, 2024 and 2023, the Company incurred net losses from continuing operations of $268.4 million and $489.9 million, respectively. The Company has historically financed its operations primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements.

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals to market its product candidates, dependence on key products, dependence on third-party service providers, such as contract research organizations, and protection of intellectual property rights. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and may require additional capital to fully implement its business plan.

The Company expects its existing cash, cash equivalents, and marketable securities 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, 2024 filed with the SEC. The unaudited condensed consolidated balance sheet at March 31, 2024 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 adjustments, which include only normal 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. Operating results for the six months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2025, 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 noncontrolling interest's proportionate share of the respective operations. 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 the 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.

In September 2024, the Company's subsidiary, Dermavant Sciences Ltd. ("Dermavant") entered into an Agreement and Plan of Merger (the "Merger Agreement") with Organon & Co. ("Organon"), Organon Bermuda Ltd., an indirect wholly owned subsidiary of Organon ("Merger Sub"), and us, solely in our capacity as the representative of the securityholders of Dermavant. Organon's acquisition of Dermavant (the "Dermavant Transaction") was completed in October 2024, subsequent to quarter end. The Company determined that the anticipated acquisition of Dermavant by Organon met the held for sale and discontinued operations accounting criteria in the second fiscal quarter of 2024. Accordingly, the Company classified the results of Dermavant as discontinued operations in its condensed consolidated statements of operations for all periods presented. Additionally, Dermavant's assets and liabilities are classified as held for sale and discontinued operations in the condensed consolidated balance sheets for all periods presented. The cash flows related to discontinued operations have not been segregated and are included in the condensed consolidated statements of cash flows. The discussions in these notes to the condensed consolidated financial statements relate solely to the Company's continuing operations, unless otherwise noted. For further discussion of the discontinued operation related to Dermavant, refer to Note 6, "Discontinued Operations."

(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, cash equivalents, and marketable securities. The Company maintains cash deposits, cash equivalents, and marketable securities 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.

(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 equivalents consist of amounts invested in money market funds and United States ("U.S.") Treasury securities.

Cash as reported in the accompanying 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, 2024	March 31, 2024
Cash and cash equivalents	$ 1,958,633	$ 6,494,953
Restricted cash (included in "Other current assets")	3,112	3,067
Restricted cash (included in "Other assets")	8,169	8,169
Cash, cash equivalents and restricted cash	$ 1,969,914	$ 6,506,189

Cash and restricted cash held by Dermavant are included in assets of discontinued operations at September 30, 2024 and March 31, 2024. Refer to Note 6, "Discontinued Operations" for further details.

(E) Marketable Securities

The Company considers all highly liquid investments in securities with original maturities of greater than three months at the time of purchase to be marketable securities. Marketable securities consist of amounts invested in U.S. Treasury securities. As of September 30, 2024, all of the Company's marketable securities had maturities less than one year from the date of purchase. All of the Company's marketable securities are classified as held-to-maturity as the Company has the ability and intent to hold to maturity and are reported at amortized cost. Interest income is recorded as earned within "Interest income" in the condensed consolidated statements of operations.

(F) Contingencies

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

(G) Investments

Investments in equity securities for which the Company does not have control or significant influence may be accounted for using (i) the fair value option, if elected, (ii) fair value through earnings, if fair value is readily determinable or (iii) for equity investments without readily determinable fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

The Company has elected the fair value option to account for certain investments over which the Company has significant influence. The Company believes the fair value option best reflects the underlying economics of the investment. See Note 4, "Equity Method Investments."

(H) Fair Value Measurements

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

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

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

The Company's financial instruments include shares of common stock of Arbutus Biopharma Corporation ("Arbutus"); Class A units of Heracles Parent, L.L.C. ("Datavant"); liability instruments issued, including the earn-out shares liabilities issued in connection with the Company's business combination with MAAC (as discussed in Note 12, "Earn-Out Shares"); its investments in other entities; cash; cash equivalents, consisting of money market funds and U.S. Treasury securities; marketable securities, consisting of U.S. Treasury securities; and accounts payable.

The shares of Arbutus common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. The Class A units of Datavant and liability instruments issued are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. Cash 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. Held-to-maturity securities are recorded at amortized cost.

(I) 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, 2024.

(J) Recently Adopted Accounting Pronouncements

The Company did not adopt any material accounting pronouncements during the six months ended September 30, 2024.

(K) Recently Issued Accounting Pronouncements

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

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

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

Note 3—Cash, Cash Equivalents, and Marketable Securities

Cash, cash equivalents, and marketable securities consisted of the following (in thousands):

	September 30, 2024	March 31, 2024
Cash and cash equivalents		
Cash	$ 123,483	$ 182,665
Money market funds	1,475,462	6,312,288
U.S. Treasury securities	359,688	—
Total cash and cash equivalents	$ 1,958,633	$ 6,494,953
Marketable securities		
U.S. Treasury securities	$ 3,428,021	$ —
Total marketable securities	$ 3,428,021	$ —
Total cash, cash equivalents, and marketable securities	$ 5,386,654	$ 6,494,953

Cash held by Dermavant is included in assets of discontinued operations at September 30, 2024 and March 31, 2024. Refer to Note 6, "Discontinued Operations" for further details.

The following table summarizes the unrealized positions for the Company's held-to-maturity securities (in thousands):

	As of September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 3,787,709	$ 8,532	$ (91)	$ 3,796,150

The Company classified its marketable securities as Level 2 measurements within the fair value hierarchy. As of September 30, 2024, the contractual maturities of all marketable securities were less than 12 months.

Note 4—Equity Method Investments

The Company maintains equity method investments in certain entities. As of September 30, 2024 and March 31, 2024, the most significant of these were the Company's investments in Arbutus and Datavant, which are accounted for using the fair value option.

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

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, 2024, RSL held approximately 21% of issued and outstanding shares of Arbutus.

At September 30, 2024 and March 31, 2024, the aggregate fair value of the Company's investment in Arbutus was $149.6 million and $100.2 million, respectively. During the three and six months ended September 30, 2024, the Company recognized unrealized gains of $29.5 million and $49.3 million on its investment in Arbutus, respectively, in the accompanying condensed consolidated statements of operations. 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 . The fair value of the Company's investment was determined using the closing price of Arbutus's common stock on September 30, 2024 and March 31, 2024 of $3.85 and $2.58, respectively.

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ 1,339	$ 4,658	$ 3,065	$ 9,309
Loss from operations	$ (21,440)	$ (21,558)	$ (43,023)	$ (39,943)
Net loss	$ (19,717)	$ (20,104)	$ (39,513)	$ (37,198)

Investment in Datavant

The Company holds an investment in Class A units of Datavant. As of September 30, 2024, the Company's minority equity interest represented approximately 9% of the outstanding Class A units in Datavant. Datavant's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion rights. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted.

As of September 30, 2024 and March 31, 2024, the fair value of the Company's investment was $161.8 million and $147.5 million, respectively. During the three and six months ended September 30, 2024, the Company recognized unrealized gains of $18.9 million and $ 14.3 million on its investment in Datavant, respectively, in the accompanying condensed consolidated statements of operations. During the three and six months ended September 30, 2023, the Company recognized unrealized losses of $35.1 million and $14.3 million on its investment in Datavant, 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 5—Recent Transactions and Developments

Telavant Disposition

On December 14, 2023 (the "Transaction Date"), the Company completed the sale of its entire equity interest in its majority-owned subsidiary Telavant to Roche Holdings, Inc. ("Roche") (the "Roche Transaction"). The Roche Transaction was made pursuant to a Stock Purchase Agreement dated October 22, 2023 among the Company, Telavant, Pfizer Inc. ("Pfizer"), and Roche (the "Stock Purchase Agreement"). Telavant was jointly formed by the Company and Pfizer in November 2022 to develop and commercialize RVT-3101, an anti-TL1A antibody in development for ulcerative colitis ("UC") and Crohn's disease, in the U.S. and Japan. Prior to the Roche Transaction, the Company held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer owned the remaining 25%, in each case on an as-converted basis.

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

In June 2024, the one-time milestone was achieved. Accordingly, the Company received $110.4 million in cash for its pro rata portion of the milestone payment in August 2024. The Company recognized a gain on sale of Telavant net assets of $110.4 million related to the one-time milestone payment during the six months ended September 30, 2024.

Note 6—Discontinued Operations

In September 2024, Dermavant entered into the Merger Agreement with Organon, Merger Sub, and us, solely in our capacity as the representative of the securityholders of Dermavant. Organon's acquisition of Dermavant was completed in October 2024, subsequent to quarter end.

Organon agreed to acquire Dermavant for aggregate cash consideration comprising (i) a payment of $175.0 million payable at the closing of the Dermavant Transaction, subject to certain adjustments, (ii) a $75.0 million milestone payment payable upon FDA approval of VTAMA (the "Product") for the treatment of atopic dermatitis and (iii) up to $950.0 million in additional milestone payments payable upon achievement of certain tiered net sales amounts with respect to the Product, each less than or equal to $1.0 billion. Additionally, Organon agreed to make tiered royalty payments of (x) low-to-mid single digit percentages with respect to annual net sales of the Product up to $1.0 billion and (y) 30% with respect to annual net sales of the Product above $1.0 billion. Such consideration and royalty payments are payable to all of Dermavant's equity holders, including holders of restricted stock units, options and warrants, on a pro rata basis relative to their ownership of Dermavant prior to the closing of the Dermavant Transaction (in each case, after giving effect to the liquidation preference of Dermavant's preference shares, all of which are held by the Company, and otherwise in accordance with the applicable terms of such securities). Under the liquidation preference of Dermavant's preference shares, the Company is entitled to receive 100% of the first $270.0 million of consideration paid pursuant to the Merger Agreement. The Company received $183.6 million in cash in October 2024 upon the closing of the Dermavant Transaction.

As contemplated by the Merger Agreement, in connection with the closing of the Dermavant Transaction, Dermavant repaid all amounts outstanding or otherwise payable (including accrued interest and all premiums and exit fees) pursuant to a senior secured credit facility (the "Credit Facility"), dated as of May 14, 2021 and amended as of May 24, 2024, by and among Dermavant, certain subsidiaries of Dermavant, XYQ Luxco S.A.R.L. and U.S. Bank Trust Company, National Association, and terminated the Credit Facility in accordance with its terms.

Following the closing of the Dermavant Transaction, all rights and obligations under each of (A) the Revenue Interest Purchase and Sale Agreement, dated as of May 14, 2021 and amended as of May 24, 2024, by and among Dermavant, Dermavant Sciences GmbH, XYQ Luxco S.A.R.L., NovaQuest Co-Investment Funds XVII, L.P., MAM Tapir Lender, LLC and U.S. Bank Trust Company, National Association and (B) the Funding Agreement, dated as of July 10, 2018 and amended as of May 24, 2024, by and among Dermavant, Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P. were retained by Dermavant and its subsidiaries, which became indirect wholly owned subsidiaries of Organon.

As a result of the Dermavant Transaction, the Company accounted for the assets and liabilities of Dermavant as assets and liabilities of discontinued operations at September 30, 2024 and March 31, 2024. Assets and liabilities of Dermavant are presented as "Current assets of discontinued operations," "Noncurrent assets of discontinued operations," "Current liabilities of discontinued operations," and "Noncurrent liabilities of discontinued operations" on the accompanying consolidated balance sheets as of September 30, 2024 and March 31, 2024. All assets and liabilities of Dermavant were classified as current as of September 30, 2024 based on the anticipated completion date of the acquisition.

Financial results of Dermavant are presented as "(Loss) income from discontinued operations, net of tax" in the accompanying consolidated statements of operations for the three and six months ended September 30, 2024 and 2023.

The following table presents components of discontinued operations included in "(Loss) income from discontinued operations, net of tax" (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	2023	2024	2023
Product revenue, net	$ 20,936	$ 18,424	$ 39,303	$ 35,083
License, milestone and other revenue	3,851	15,029	32,626	15,511
Revenue, net	24,787	33,453	71,929	50,594
Operating expenses:				
Cost of revenues	6,656	3,043	10,421	6,274
Research and development	8,396	17,194	21,097	32,911
Selling, general and administrative	45,503	75,779	94,129	140,687
Total operating expenses	60,555	96,016	125,647	179,872
Loss from operations	(35,768)	(62,563)	(53,718)	(129,278)
Change in fair value of debt	16,700	9,744	(102,652)	24,078
Interest expense[1]	6,469	9,247	19,868	18,159
Other (income) expense, net	(16,658)	4,401	(18,440)	(3,019)
(Loss) income from discontinued operations before income taxes	(42,279)	(85,955)	47,506	(168,496)
Income tax expense	804	521	1,496	598
(Loss) income from discontinued operations, net of tax	$ (43,083)	$ (86,476)	$ 46,010	$ (169,094)
Loss from discontinued operations before income taxes attributable to noncontrolling interests	$ —	$ (374)	$ (155)	$ (733)
(Loss) income from discontinued operations before income taxes attributable to Roivant Sciences Ltd.	(42,279)	(85,581)	47,661	(167,763)
(Loss) income from discontinued operations before income taxes	$ (42,279)	$ (85,955)	$ 47,506	$ (168,496)

(1) Interest expense consists of interest payments related to outstanding debt held by Dermavant as well as the associated non-cash amortization of debt discounts and issuance costs.

The following table presents the major classes of Dermavant's assets and liabilities that were reclassified as assets and liabilities of discontinued operations (in thousands):

	September 30, 2024	March 31, 2024[1]
Assets:		
Cash and cash equivalents	$ 55,448	$ 40,753
Property and equipment, net	2,881	3,736
Operating lease right-of-use assets	2,465	2,890
Intangible assets, net	142,311	137,842
Other assets	117,134	116,925
Total assets of discontinued operations	$ 320,239	$ 302,146
Liabilities:		
Accounts payable	$ 10,709	$ 39,196
Accrued expenses	50,342	56,169
Operating lease liabilities	2,717	3,172
Long-term debt	335,501	442,591
Other liabilities	1,944	3,222
Total liabilities of discontinued operations	$ 401,213	$ 544,350

(1) Includes both current and non-current assets and liabilities of discontinued operations.

In the accompanying consolidated statements of cash flows, the cash flows from discontinued operations are not separately classified. The following table summarizes significant non-cash operating and investing items from discontinued operations (in thousands):

	Six Months Ended September 30,	
	2024	2023
Share-based compensation	$ 5,055	$ 6,133
Change in fair value of debt	$ (102,652)	$ 24,078
Depreciation and amortization	$ 5,761	$ 5,703

Note 7—Certain Balance Sheet Components

(A) Other Current Assets

Other current assets at September 30, 2024 and March 31, 2024 consisted of the following (in thousands):

	September 30, 2024	March 31, 2024
Prepaid expenses	$ 54,843	$ 33,779
Trade receivables, net	1,916	3,990
Restricted cash	3,112	3,067
Income tax receivable	6,889	1,316
Interest receivable	13,879	27,441
Other	13,587	11,012
Total other current assets	$ 94,226	$ 80,605

(B) Accrued Expenses

Accrued expenses at September 30, 2024 and March 31, 2024 consisted of the following (in thousands):

	September 30, 2024	March 31, 2024
Research and development expenses	$ 56,299	$ 37,712
Compensation-related expenses	38,849	49,890
Other expenses	16,321	31,815
Total accrued expenses	$ 111,469	$ 119,417

(C) Other Current Liabilities

Other current liabilities at September 30, 2024 and March 31, 2024 consisted of the following (in thousands):

	September 30, 2024	March 31, 2024
Deferred revenue	$ 3,411	$ 4,168
Income tax payable	5,413	9,773
Other	97	—
Total other current liabilities	$ 8,921	$ 13,941

Note 8—Shareholders' Equity

(A) At-the-Market Equity Offering Program

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

As of September 30, 2024, the Company had $400.0 million of remaining capacity available under the ATM Facility.

(B) Share Repurchase Program

The Company's board of directors authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses). The repurchase program is funded by available cash and cash equivalents on hand and does not have an expiration date. In April 2024, pursuant to the share repurchase program, the Company entered into a share repurchase agreement with Sumitomo Pharma Co., Ltd. ("Sumitomo") and repurchased all 71,251,083 common shares held by Sumitomo at a purchase price per share of $9.10, for an aggregate purchase price of approximately $648.4 million. Repurchases of an additional 9,023,658 shares were made in open market transactions under the share repurchase program in the three months ended September 30, 2024 for an aggregate purchase price of approximately $106.1 million.

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, 2024, a total of 42,237,212 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, 2024 was as follows:

	Number of Options
Options outstanding at March 31, 2024	147,068,607
Granted	4,239,920
Exercised	(3,394,492)
Forfeited/Canceled	(1,663)
Options outstanding at September 30, 2024	147,912,372
Options exercisable at September 30, 2024	107,641,231

Restricted Stock Units and Performance Stock Units

Activity for restricted stock units ("RSUs") and performance stock units under the RSL Equity Plans for the six months ended September 30, 2024 was as follows:

	Number of Shares
Non-vested balance at March 31, 2024	16,778,211
Granted	39,243,918
Vested	(3,609,683)
Forfeited	(400,610)
Non-vested balance at September 30, 2024	52,011,836

Multi-Year Incentive Compensation Program

In July 2024, the Compensation Committee of the Board of Directors approved a multi-year incentive compensation program for each of Matthew Gline, Chief Executive Officer; Mayukh Sukhatme, President and Chief Investment Officer; and Eric Venker, President and Chief Operating Officer (the "2024 Senior Executive Compensation Program"). The program primarily consists of two key components: (i) one-time cash retention awards (refer to Note 11, "Commitments and Contingencies" for further details regarding the one-time cash retention awards) and (ii) long-term equity incentive awards granted in the form of performance restricted stock units ("PSUs") with both a performance- and a time-vesting component, time-vesting restricted stock units, and time-vesting stock options.

A summary of the long-term equity incentive awards approved is as follows:

Executive	Title	Performance Restricted Stock Units (at max)	Restricted Stock Units	Stock Options
Matthew Gline	Chief Executive Officer	14,450,000	2,754,821	—
Mayukh Sukhatme	President and Chief Investment Officer	17,000,000	1,836,547	—
Eric Venker	President and Chief Operating Officer	*	204,000	409,000

* The Company entered into a letter agreement pursuant to which Dr. Venker may be granted up to 11,900,000 PSUs in the future, in the sole discretion of the Compensation Committee of the Board of Directors.

The stock options and performance stock options table above includes the stock options granted to Dr. Venker pursuant to the 2024 Senior Executive Compensation Program with a total grant date fair value of $2.9 million. The RSUs and PSUs table above includes the RSUs granted to Mr. Gline, Dr. Sukhatme, and Dr. Venker and PSUs granted to Mr. Gline and Dr. Sukhatme pursuant to the 2024 Senior Executive Compensation Program with total grant date fair values of $51.8 million and $278.2 million, respectively.

The PSUs granted to Mr. Gline and Dr. Sukhatme consist of six vesting tranches, with the number of PSUs allocated to each such tranche set forth in the table below. Each tranche of PSUs will vest on the first date that both of the "Service Condition" and the "Performance Condition" applicable to such tranche has been satisfied. The "Performance Condition" will be deemed satisfied for each tranche on the first date, during the performance period ending on the five-year anniversary of the grant date (the "Performance Period"), when the Company's trailing 30-day volume weighted average trading price per share ("30-Day VWAP") for trading days during the Performance Period exceeds the specified share price hurdle set forth in the table below:

Tranche	% of PSUs	Share Price Hurdle (per share)
First Tranche	14.71%	$ 15.00
Second Tranche	7.35%	$ 17.50
Third Tranche	8.82%	$ 20.00
Fourth Tranche	11.77%	$ 22.50
Fifth Tranche	22.06%	$ 25.00
Sixth Tranche	35.29%	$ 30.00

The "Service Condition" with respect to each tranche will be deemed satisfied on the first anniversary of the date on which the Performance Condition is first satisfied with respect to such tranche, subject to the executive's continuous service through such anniversary. Following the achievement of the Service Condition and the vesting of any tranche of the PSUs, the common shares underlying the applicable vested tranche of PSUs are subject to a further two-year holding period before such common shares may be sold by the executive (subject to certain exceptions).

The Company estimated the fair value of the PSUs on the date of grant using a Monte Carlo simulation applying the assumptions in the following table:

Assumptions	
Expected stock price volatility	70.0%
Expected risk free interest rate	4.1%
Stock price	$ 10.80

As the PSUs are subject to the market performance of the Company's stock price, share-based compensation expense is recognized over the requisite service period regardless of whether the market condition is ultimately satisfied, subject to continued service over the period. The Company recognized share-based compensation related to PSUs of $21.9 million during the three and six months ended September 30, 2024. At September 30, 2024, total unrecognized compensation expense related to non-vested PSUs granted pursuant to the 2024 Senior Executive Compensation Program was $256.3 million. The Company has not recognized share-based compensation expense for potential PSU awards to Dr. Venker as these have not been granted by the Compensation Committee of the Board of Directors.

The grant date fair value of the PSUs is sensitive to the expected stock price volatility of the Company's shares. The Company selected a volatility estimate of 70.0% based on the observed historical volatility of the Company's shares. If a higher volatility estimate of 80% were selected, the total grant date fair value of the PSUs would be approximately $292.9 million. If a lower volatility estimate based on the implied volatility of the Company's shares of 41.6% were selected, the total grant date fair value of the PSUs would be approximately $202.4 million. If a volatility estimate based on an average of the historical and implied volatility of 55.8% were selected, the total grant date fair value of the PSUs would be approximately $247.3 million.

Capped Value Appreciation Rights

March 2020 CVAR Grants

As of September 30, 2024, 17,548,368 capped value appreciation rights ("CVARs") granted in March 2020 remain outstanding. These CVARs had met the service vesting condition as of September 30, 2024 but have not satisfied their applicable hurdle price on an applicable hurdle measurement date. Such CVARs will be earned if the hurdle price is satisfied on a hurdle measurement date, being March 30, prior to the expiration date of March 31, 2026.

November 2021 CVAR Grants

Activity for CVARs granted in November 2021 under the RSL 2021 EIP for the six months ended September 30, 2024 was as follows:

	Number of CVARs
Non-vested balance at March 31, 2024	1,782,078
Vested	(585,769)
Forfeited	(128,829)
Non-vested balance at September 30, 2024	1,067,480

During the six months ended September 30, 2024, 585,769 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 $13.9 million and $28.6 million for the three and six months ended September 30, 2024, respectively, and $11.8 million and $23.7 million for the three and six months ended September 30, 2023, respectively, related to subsidiary EIPs.

Note 10—Income Taxes

The Company's effective tax rate for the three and six months ended September 30, 2024 was (5.6)% and (10.0)%, respectively, and the effective tax rate for the three and six months ended September 30, 2023 was (1.3)% and (1.0)%, respectively. The effective tax rate for the six months ended September 30, 2024 is driven by the Company's gain on sale of Telavant's net assets, which qualifies for the substantial shareholding exemption in the U.K. and consequently is not subject to the corporation income tax, as well as earnings by jurisdiction and a valuation allowance that eliminates the Company's global net deferred tax assets. For all other periods disclosed, 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

Lease Commitments

The Company has leases, consisting primarily of real estate leases. Refer to Note 13, "Leases" in the Company's Annual Report on Form 10-K for the year ended March 31, 2024 for further information regarding the Company's lease commitments.

In September 2024, the Company's subsidiary, Roivant Sciences, Inc. ("RSI"), entered into a lease agreement (the "RSI Lease Agreement") with One Penn Plaza LLC for office space in New York, NY to serve as the future U.S. corporate headquarters of RSI. The RSI Lease Agreement has an expected commencement date on or after December 14, 2024 and will expire on or after July 31, 2041 with an option to extend. The approximate future minimum obligation under this lease is $115.0 million, and RSI is eligible to receive a credit of $1.8 million. As of September 30, 2024, a lease commencement date in accordance with ASC 842, *Leases*, had not occurred. As such, no lease liability or right-of-use asset relating to the RSI Lease Agreement has been recorded.

Other Commitments

The Company has entered into commitments under various asset acquisition and license agreements. Under these agreements, the Company is 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 the achievement of specified development, regulatory and commercial milestones, and the Company will be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements. Refer to Note 14, "Commitments and Contingencies" in the Company's Annual Report on Form 10-K for the year ended March 31, 2024 for further information regarding certain key asset acquisition and license agreements. There have been no material changes to the key asset acquisition and license agreements relating to continuing operations during the six months ended September 30, 2024. The Company has further commitments relating to other asset acquisition and license agreements entered and expects to enter into additional asset acquisition and license agreements in the future, which may require upfront payments and long-term commitments of capital resources.

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

In November 2021, the Company's subsidiary, Immunovant, entered into a Product Service Agreement ("PSA") with Samsung Biologics Co., Ltd. ("Samsung"), pursuant to which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale, if approved, and perform other manufacturing-related services with respect to batoclimab. Upon execution of the PSA, Immunovant committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition, Immunovant has a minimum obligation to purchase further batches of batoclimab in the four-year period of 2026 through 2029. As of September 30, 2024, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $43.6 million.

Cash Bonus Program

During the year ended March 31, 2024, the Company approved a special one-time cash retention bonus award to its employees in the aggregate amount of $79.7 million (the "Cash Bonus Program"). During the three months ended September 30, 2024, the Company recognized general and administrative expense and research and development expense of $6.6 million and $1.9 million, respectively, and during the six months ended September 30, 2024, the Company recognized general and administrative expense and research and development expense of $13.5 million and $3.7 million, respectively, relating to the Cash Bonus Program.

Multi-Year Incentive Compensation Program

Pursuant to the 2024 Senior Executive Compensation Program, the Compensation Committee of the Board of Directors approved the following one-time cash retention awards in July 2024:

Executive	Title	Cash Awards (in thousands)
Matthew Gline	Chief Executive Officer	$ 5,725
Mayukh Sukhatme	President and Chief Investment Officer	$ 80,550
Eric Venker	President and Chief Operating Officer	$ 7,465

Mr. Gline and Dr. Venker received 75% of their respective cash retention awards as of September 30, 2024. The remaining 25% of the award will vest and become payable on or about September 19, 2025, in each case subject to the executive's continuous service through the applicable vesting date.

The cash retention award provided to Dr. Sukhatme was paid in full as of September 30, 2024. If a Recoupment Event (as defined below) occurred on or prior to September 30, 2024, Dr. Sukhatme would have been required to repay to the Company $30.0 million of the retention award. If a Recoupment Event (as defined below) occurs on or prior to September 30, 2025 (but on or after October 1, 2024), Dr. Sukhatme will be required to repay to the Company $15.0 million of the retention award. A "Recoupment Event" will be deemed to occur if (x) Dr. Sukhatme's employment in good standing is terminated or otherwise ceases for any reason (except as provided in the following sentence) or (y) Dr. Sukhatme breaches any of his restrictive covenant obligations. In the event Dr. Sukhatme's employment is terminated by the Company without "cause" (as defined in Dr. Sukhatme's employment agreement) or due to death or disability, no portion of the cash retention award will be subject to repayment, provided that Dr. Sukhatme executes and does not revoke a release of claims. There was no Recoupment Event as of September 30, 2024.

As a result of the cash retention rewards, the Company recognized general and administrative expense of $79.1 million during the three and six months ended September 30, 2024. The remaining portion of $14.6 million as of September 30, 2024 will be recognized over the applicable service periods.

(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.

(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 accompanying condensed consolidated financial statements as of September 30, 2024 and March 31, 2024.

Note 12—Earn-Out Shares

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

- 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).

- 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).

- The remaining number of common shares issued to the MAAC Sponsor and each of MAAC's independent directors are not subject to the vesting conditions described above (the "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 accompanying 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, 2024, no Earn-Out Shares have vested.

The Earn-Out Shares are subject to certain lock-up agreements pursuant to which, among other things, the MAAC Sponsor and each of MAAC's independent directors (the "MAAC Independent Directors") have agreed not to effect any sale or distribution of the Company's common shares during the applicable lock-up period, subject to customary exceptions. The lock-up periods applicable to the Company's common shares, including Earn-Out Shares, held by the MAAC Sponsor and MAAC Independent Directors as of immediately following the closing of the Business Combination (the "Closing") are (i) with respect to 25% of the Company's common shares held by the MAAC Sponsor and MAAC Independent Directors, six months following the Closing, which expired on March 30, 2022, (ii) with respect to an additional 25% of the Company's common shares held by the MAAC Sponsor and MAAC Independent Directors, the earlier of twelve months following the achievement of certain price-based vesting restrictions or six years from the Closing and (iii) with respect to 50% of the Company's common shares held by the MAAC Sponsor and MAAC Independent Directors, thirty-six months following the Closing, which expired on September 30, 2024.

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, 2024 and March 31, 2024, by level, within the fair value hierarchy (in thousands):

	As of September 30, 2024				As of March 31, 2024			
	Level 1	Level 2	Level 3	Balance as of September 30, 2024	Level 1	Level 2	Level 3	Balance as of March 31, 2024
Assets:								
Money market funds	$ 1,475,462	$ —	$ —	$ 1,475,462	$ 6,312,288	$ —	$ —	$ 6,312,288
Investment in Datavant Class A units	—	—	161,791	161,791	—	—	147,526	147,526
Investment in Arbutus common shares	149,563	—	—	149,563	100,227	—	—	100,227
Total assets at fair value	$ 1,625,025	$ —	$ 161,791	$ 1,786,816	$ 6,412,515	$ —	$ 147,526	$ 6,560,041
Liabilities:								
Liability instruments measured at fair value[(1)]	$ —	$ —	$ 26,252	$ 26,252	$ —	$ —	$ 25,737	$ 25,737
Total liabilities at fair value	$ —	$ —	$ 26,252	$ 26,252	$ —	$ —	$ 25,737	$ 25,737

(1) At September 30, 2024, Level 3 includes the fair value of the Earn-Out Shares of $23.8 million and other liability instruments issued of $2.5 million. At March 31, 2024, Level 3 includes the fair value of the Earn-Out Shares of $22.0 million and other liability instruments issued of $3.7 million.

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, 2024.

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, 2024 and 2023 were as follows (in thousands):

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
Balance at March 31, 2024	$ 147,526
Changes in fair value of investment in Datavant, included in net loss	14,265
Balance at September 30, 2024	$ 161,791

The changes in fair value of the Level 3 liabilities during the six months ended September 30, 2024 and 2023 were as follows (in thousands):

Balance at March 31, 2023	$ 33,651
Exercise of Private Placement Warrants	(28,090)
Changes in fair value of liability instruments, included in net loss	25,553
Balance at September 30, 2023	$ 31,114
Balance at March 31, 2024	$ 25,737
Changes in fair value of liability instruments, included in net loss	515
Balance at September 30, 2024	$ 26,252

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, 2024**	**As of March 31, 2024**
Volatility	90.0%	90.0%
Risk-free rate	3.71%	4.86%

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. Refer to Note 12, "Earn-Out Shares" 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, 2024**	**As of March 31, 2024**
Volatility	54.7%	63.2%
Risk-free rate	3.66%	4.50%

As of September 30, 2024 and March 31, 2024, the fair value of the Earn-Out Shares was $23.8 million and $22.0 million, respectively. Earn-Out Shares were included in "Liability instruments measured at fair value" in the accompanying condensed consolidated balance sheets.

Note 14—Net (Loss) Income per Common Share

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

For periods of loss from continuing operations, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common stock equivalents is anti-dilutive. 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 from continuing operations.

As of September 30, 2024 and 2023, the following potentially dilutive common stock equivalents were excluded from the computation of diluted net (loss) income per common share:

	September 30, 2024	September 30, 2023
Stock options and performance stock options	147,912,372	148,753,920
Restricted stock units and performance stock units (non-vested)	52,011,836	20,073,411
March 2020 CVARs[(1)]	17,548,368	28,753,677
November 2021 CVARs (non-vested)	1,067,480	2,506,499
Restricted common stock (non-vested)	210,918	487,005
Earn-Out Shares (non-vested)	3,080,387	3,080,387
Other stock based awards and instruments issued	5,032,786	5,611,820

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

Note 15—Subsequent Events

Organon’s acquisition of Dermavant was completed in October 2024. Refer to Note 6, “Discontinued Operations” for further details.

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, 2024, included in our Annual Report on Form 10-K, filed with the SEC on May 30, 2024 (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 biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Roivant's pipeline includes IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting FcRn in development across several IgG-mediated autoimmune indications; brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 in development for the treatment of dermatomyositis and non-infectious uveitis; mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease; and namilumab, an anti-GM-CSF monoclonal antibody in development for the treatment of pulmonary sarcoidosis. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business.

The following table summarizes selected product candidates from our pipeline.

Product Candidate	Indication	Vant	Modality	Phase
IMVT-1402	Graves' Disease	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Difficult-to-Treat Rheumatoid Arthritis	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Myasthenia Gravis	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Indication 5	Immunovant	Biologic	Phase 2/3*
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 3*
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 3*
Batoclimab	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2b*
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Non-Infectious Uveitis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Other Indications	Priovant	Small Molecule	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 2*
Mosliciguat	Pulmonary Hypertension associated with Interstitial Lung Disease	Pulmovant	Inhaled	Phase 2

Note: All product candidates in our current pipeline are investigational and subject to health authority approval. The "Phase" for a specific product candidate referenced above reflects both ongoing clinical trials and expected upcoming trials.

** Indicates registrational or potentially registrational trials.*

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of September 30, 2024, as well as our ownership interest in potential future milestones and royalties related to the Dermavant Transaction (see footnote 4 below).

Vant / Milestones & Royalties	Roivant Ownership Basic[1]	Roivant Ownership Fully Diluted[2]
Immunovant	54%[3]	48%[3]
Priovant	75%	67%
Genevant	83%	64%
Kinevant	99%	98%
Pulmovant	100%	93%
Covant	100%	87%
Psivant	48%	44%
Arbutus	21%[3]	19%[3]
Lokavant	57%	50%
VantAI	60%	49%
Datavant	†	†
VTAMA Milestones & Royalties[4]	86%[4]	81%[4]

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.*

4. *Amounts shown as of the closing of the Dermavant Transaction on October 28, 2024. At closing of the Dermavant Transaction, we received cash consideration of $183.6 million and are entitled to receive an additional cash payment of $75.0 million upon FDA approval of VTAMA for the treatment of atopic dermatitis (the "AD Approval Milestone"). In addition to the foregoing, at closing, all former Dermavant equity holders, including Roivant, received the right to receive their pro rata portion of (i) milestone payments of up to $950 million for the achievements of certain tiered net sales amounts with respect to VTAMA, each less than or equal to $1 billion and (ii) and tiered royalties of (x) low-to-mid single digit percentages with respect to annual net sales of VTAMA up to $1 billion and (y) 30% with respect to annual net sales of VTAMA above $1 billion. Roivant's ownership interest in these potential future milestones and royalties consists of (i) 100% of the first $270 million in upfront, milestone and royalty payments (inclusive of the upfront payment made at closing and the potential AD Approval Milestone) and (ii) between 86% and 81% of subsequent milestone and royalty payments. For more information on the Dermavant Transaction, please refer to Note 6—Discontinued Operations to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.*

† *As of September 30, 2024, the Company's minority equity interest in Datavant represented approximately 9% of the outstanding Class A units. Datavant's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted. For more information on Roivant's ownership interest in Datavant, please refer to Note 4—Equity Method Investments to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.*

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
Roivant pipeline growth	Roivant	New mid/late-stage in-licensing announcements	Ongoing
Namilumab	Kinevant	Topline data from Phase 2 trial in sarcoidosis	4Q 2024
LNP Platform	Genevant	Markman hearing in Pfizer/BioNTech case	4Q 2024
Batoclimab	Immunovant	Topline data from Phase 3 trial in myasthenia gravis	By FY End
Batoclimab	Immunovant	Initial data from period 1 of Phase 2B trial in chronic inflammatory demyelinating polyneuropathy	By FY End
LNP Platform	Genevant	Summary judgment phase in Moderna case	2Q-3Q 2025
LNP Platform	Genevant	Trial in Moderna case	2H 2025
Batoclimab	Immunovant	Topline data from Phase 3 trials in thyroid eye disease	2H 2025
Brepocitinib	Priovant	Topline data from Phase 3 trial in dermatomyositis	2H 2025
Mosliciguat	Pulmovant	Topline data from Phase 2 trial in pulmonary hypertension associated with interstitial lung disease	2H 2026

Note: References under "Expected Timing" are to calendar years unless otherwise noted. References to "FY End" are to Roivant's fiscal year ending March 31, 2025. All catalyst timings are based on current expectations and, where applicable, contingent on FDA feedback, and may be subject to change. The timing of the litigation-related events noted above is subject to change, including at the discretion of the court.

Recent Developments

- **Immunovant:**

  Endocrinology Program
  In September 2024, Immunovant reported additional positive results from the Phase 2a trial of batoclimab in Graves' Disease. Participants in the trial received 12 weeks of high dose batoclimab, 680 mg weekly by subcutaneous injection (SC) followed by 12 weeks of lower dose batoclimab, 340 mg weekly SC. At the end of the first 12 weeks, participants experienced a mean IgG reduction of 77% leading to a 76% Response rate. In addition, by the end of 12 weeks of higher dose batoclimab, 56% achieved an ATD-Free Response. During Weeks 13 to 24, the lower 340mg dose of batoclimab resulted in mean IgG reduction of 65% (vs. 77% on 680mg dose) with a correspondingly lower responder rate of 68%. In addition, a lower ATD-Free Response rate of 36% was also observed in the second 12 weeks. Patients who achieved at least a 70% IgG reduction at the end of the trial had nearly a threefold higher ATD-Free Response rate than those who did not (60% vs. 23%). Batoclimab was well tolerated with no new safety signals identified.

  In November 2024, additional data on the efficacy and safety of batoclimab in Graves' thyroidal and extrathyroidal disease were presented in an oral presentation at the American Thyroid Association (ATA) 2024 Annual Meeting. These data showed that a 60% response rate (defined as T3 and T4 falling below the upper limit of normal (ULN) without increasing the ATD dose) was achieved by Week 2, demonstrating the rapidity of response to batoclimab 680mg dosed weekly. Meaningful improvements in proptosis and lid aperture were also observed at both Week 12 and Week 24. Pronounced improvements in multiple Thyroid-Related Patient-Reported Outcomes (ThyPRO-39) measurement scales were also observed, with ATD-Free Responders (defined as T3 and T4 falling below the ULN and ceasing all ATD medications) reporting greater improvements than other participants.

  Neurology Program
  In November 2024, Immunovant announced completion of enrollment for patients included in Period 1 of the Phase 2b trial of batoclimab in CIDP, with data expected by March 31, 2025, to inform the trial design for a potentially registrational program with IMVT-1402.

  Rheumatology Program
  In November 2024, Immunovant also announced FDA clearance of the IND for IMVT-1402 in D2T RA and expects to initiate a potentially registrational trial by March 31, 2025.

- **Priovant:** In September 2024, Priovant announced receipt of Fast Track designation from FDA for brepocitinib in NIU and enrolled the first patients in the Phase 3 program. New 52-week data from the Phase 2 NEPTUNE study of brepocitinib in NIU showed potential best-in-indication efficacy sustained to one year. Treatment failure rate in the 45 mg dose arm was 35% at week 52 vs. 29% at week 24. Treatment failure rate in the 15 mg dose arm was 56% vs. 44% at week 24. In each treatment arm only one additional patient failed from week 24 to 52. Other important efficacy measurements at week 52 were consistent with the week 24 data, including measurements of retinal vascular leakage and prevention and treatment of macular edema. Safety and tolerability were consistent with prior clinical studies of brepocitinib, with no new safety or tolerability signals identified. Brepocitinib has been dosed in over 1,400 subjects and patients with a safety profile that appears consistent with approved and widely prescribed JAK inhibitors.

- **Pulmovant:** In September 2024, Roivant unveiled mosliciguat, a potential first-in-class and best-in-category inhaled once-daily sGC activator. Mosliciguat is being developed for PH-ILD, which affects ~200,000 patients in the U.S. and Europe with limited or no treatment options.

  In September 2024, Pulmovant also presented data from the Phase 1b ATMOS study showing a single dose of inhaled mosliciguat in PH patients (N=38) led to sustained, clinically meaningful mean-max reductions in PVR of up to ~38%, one of the highest reductions seen in PH trials to date. Mosliciguat was generally well-tolerated, with low rates of treatment-emergent adverse events (TEAEs).

  Pulmovant initiated the global Phase 2 PHocus trial of mosliciguat in patients with PH-ILD.

- **Roivant:** In October 2024, Roivant reported the close of Organon's acquisition of Dermavant. At closing, Roivant received $184M in cash and Organon took on all of Dermavant's remaining outstanding long-term debt, which, inclusive of Dermavant's senior credit facility repaid at closing, had a carrying value of $336M as of September 30, 2024. In addition, Organon will pay Roivant a $75M milestone upon FDA approval for VTAMA in atopic dermatitis, with a target action date in the first quarter of calendar year 2025. The transaction also includes payments of up to $950 million for the achievements of certain commercial milestones, in addition to the tiered royalties on net sales that Organon will pay Dermavant shareholders.

  Roivant continued to return capital through share repurchases with $106M purchased for the quarter ending September 30, 2024, resulting in $754M cumulative share repurchases (inclusive of the repurchase of Sumitomo's stake in April 2024) through September 30, 2024.

  Roivant reported consolidated cash, cash equivalents and marketable securities of approximately $5.4B at September 30, 2024.

Components of Results of Operations

Revenue, net

Revenue, net primarily relates to the recognition of payments received in connection with license agreements, as well as revenue generated by subscription and service-based fees.

Cost of revenues

Our cost of revenues primarily relates to subscription and service-based revenue recognized for the use of technology developed and consists primarily of employee, hosting, and third-party data costs.

Research and development expenses

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

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

- Unallocated internal costs, including:

    - employee-related expenses, such as salaries, share-based compensation, and benefits, for research and development personnel; and

    - other expenses that are not allocated to a specific program.

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

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

- the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of our product candidates, and other research and development activities that we may conduct;

- the number and scope of preclinical and clinical programs we decide to pursue;

- the uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;

- the number of doses that patients receive;

- the countries in which the trials are conducted;

- our ability to secure and leverage adequate CRO support for the conduct of clinical trials;

- our ability to establish an appropriate safety and efficacy profile for our product candidates;

- the timing, receipt and terms of any approvals from applicable regulatory authorities;

- the potential additional safety monitoring or other studies requested by regulatory agencies;

- the significant and changing government regulation and regulatory guidance;

- our ability to establish clinical and commercial manufacturing capabilities, or make arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;

- the impact of any business interruptions to our operations due to the COVID-19 pandemic or other epidemics; and
- our ability to maintain a continued acceptable safety profile of our product candidates following approval of our product candidates.

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

Acquired in-process research and development expenses

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

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

General and administrative expenses

General and administrative ("G&A") expenses consist primarily of employee-related expenses, such as salaries, share-based compensation and benefits, for employees engaged in G&A activities. G&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. G&A expenses also consist of legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations.

We expect G&A expenses to increase in future periods to support our continued research and development activities and potential commercialization efforts. These increases will likely include additional costs related to the hiring of new personnel, including higher share-based compensation expenses, and fees to outside consultants, as well as other expenses. If any of our current or future product candidates receives regulatory approval in the U.S. or another jurisdiction, we expect that we would incur significantly increased expenses associated with building a sales and marketing team. Additionally, in July 2024, the Compensation Committee of the Board of Directors approved a multi-year incentive compensation program for each of Matthew Gline, Chief Executive Officer; Mayukh Sukhatme, President and Chief Investment Officer; and Eric Venker, President and Chief Operating Officer. The long-term equity incentive awards granted pursuant to this program will result in significant increases to share-based compensation expense over the vesting period of the awards. Refer to Note 9, "Share-Based Compensation" of our financial statements for further details.

Gain on sale of Telavant net assets

Gain on sale of Telavant net assets reflects the gain resulting from the achievement of a one-time milestone in June 2024 related to the sale of our entire equity interest in our majority-owned subsidiary Telavant Holdings, Inc. ("Telavant") to Roche Holdings, Inc. ("Roche") (the "Roche Transaction"). In December 2023, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately $7.1 billion in cash at the closing of the Roche Transaction and a one-time milestone payment of $150 million in cash payable upon the initiation of a Phase 3 trial in UC. Prior to the Roche Transaction, we held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer Inc. owned the remaining 25%, in each case on an as-converted basis. The $7.1 billion in closing consideration was paid to all of Telavant's equity holders, including holders of restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction, and this same treatment will be applied to the one-time milestone payment. We recognized a gain on sale of Telavant net assets of approximately $110 million for our pro rata portion of the one-time milestone consideration during the six months ended September 30, 2024. Refer to Note 5, "Recent Transactions and Developments" for further information regarding the Roche Transaction.

Change in fair value of investments

Change in fair value of investments includes the unrealized (gain) loss on equity investments, including Arbutus Biopharma Corporation ("Arbutus") and Heracles Parent, L.L.C. ("Datavant"). We have elected the fair value option to account for these investments.

Change in fair value of liability instruments

Change in fair value of liability instruments primarily includes the (gain) loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including the 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.

Interest income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

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 and consideration of the available facts and circumstances.

(Loss) income from discontinued operations, net of tax

(Loss) income from discontinued operations, net of tax represents the financial results of Dermavant Sciences Ltd. ("Dermavant"). In September 2024, Dermavant entered into an Agreement and Plan of Merger (the "Merger Agreement") with Organon & Co. ("Organon"), Organon Bermuda Ltd., an indirect wholly owned subsidiary of Organon ("Merger Sub"), and us, solely in our capacity as the representative of the securityholders of Dermavant. Organon's acquisition of Dermavant (the "Dermavant Transaction") was completed in October 2024. Refer to Note 6, "Discontinued Operations" of our financial statements for further information.

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. We record net loss attributable to noncontrolling interests equal to the noncontrolling interest's proportionate share of the respective operations.

Results of Operations

Comparison of the three and six months ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue, net	$ 4,475	$ 3,648	$ 827
Operating expenses:			
Cost of revenues	234	223	11
Research and development	143,073	114,790	28,283
Acquired in-process research and development	—	13,950	(13,950)
General and administrative	202,881	88,576	114,305
Total operating expenses	346,188	217,539	128,649
Loss from operations	(341,713)	(213,891)	(127,822)
Change in fair value of investments	(48,375)	45,849	(94,224)
Change in fair value of liability instruments	(635)	11,789	(12,424)
Gain on deconsolidation of subsidiaries	—	(17,354)	17,354
Interest income	(69,773)	(14,299)	(55,474)
Other expense, net	1,453	1,530	(77)
Loss from continuing operations before income taxes	(224,383)	(241,406)	17,023
Income tax expense	12,458	3,236	9,222
Loss from continuing operations, net of tax	(236,841)	(244,642)	7,801
Loss from discontinued operations, net of tax	(43,083)	(86,476)	43,393
Net loss	(279,924)	(331,118)	51,194
Net loss attributable to noncontrolling interests	(49,740)	(26,791)	(22,949)
Net loss attributable to Roivant Sciences Ltd.	$ (230,184)	$ (304,327)	$ 74,143

The following table sets forth our results of operations for the six months ended September 30, 2024 and 2023:

	Six Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue, net	$ 12,465	$ 8,131	$ 4,334
Operating expenses:			
Cost of revenues	447	1,206	(759)
Research and development	263,580	224,206	39,374
Acquired in-process research and development	—	26,450	(26,450)
General and administrative	302,773	179,858	122,915
Total operating expenses	566,800	431,720	135,080
Gain on sale of Telavant net assets	110,387	—	110,387
Loss from operations	(443,948)	(423,589)	(20,359)
Change in fair value of investments	(63,601)	53,413	(117,014)
Change in fair value of liability instruments	515	51,967	(51,452)
Gain on deconsolidation of subsidiaries	—	(17,354)	17,354
Interest income	(141,900)	(31,014)	(110,886)
Other expense, net	5,061	4,357	704
Loss from continuing operations before income taxes	(244,023)	(484,958)	240,935
Income tax expense	24,421	4,911	19,510
Loss from continuing operations, net of tax	(268,444)	(489,869)	221,425
Income (loss) from discontinued operations, net of tax	46,010	(169,094)	215,104
Net loss	(222,434)	(658,963)	436,529
Net loss attributable to noncontrolling interests	(87,547)	(62,820)	(24,727)
Net loss attributable to Roivant Sciences Ltd.	$ (134,887)	$ (596,143)	$ 461,256

Variance analysis for three and six months ended September 30, 2024 and 2023

Revenue, net

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Revenue, net	$ 4,475	$ 3,648	$ 827	$ 12,465	$ 8,131	$ 4,334

Revenue, net increased by $0.8 million to $4.5 million for the three months ended September 30, 2024, compared to $3.6 million for the three months ended September 30, 2023. Revenue, net was not significant in either period presented.

Revenue, net increased by $4.3 million to $12.5 million for the six months ended September 30, 2024, compared to $8.1 million for the six months ended September 30, 2023, Revenue, net was not significant in either period presented.

Cost of revenues

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Cost of revenues	$ 234	$ 223	$ 11	$ 447	$ 1,206	$ (759)

Cost of revenues was $0.2 million for each of the three months ended September 30, 2024 and 2023. Cost of revenues was not significant in either period presented.

Cost of revenues decreased by $0.8 million to $0.4 million for the six months ended September 30, 2024, compared to $1.2 million for the six months ended September 30, 2023. Cost of revenues was not significant in either period presented.

Research and development expenses

For the three months ended September 30, 2024 and 2023**,** our research and development expenses consisted of the following:

	Three Months Ended September 30,		
	2024	**2023[1]**	**Change**
		(in thousands)	
Program-specific costs:			
Anti-FcRn franchise—neurological diseases	$ 29,614	$ 5,133	$ 24,481
Anti-FcRn franchise—endocrine diseases	14,887	8,431	6,456
Anti-FcRn franchise—rheumatology diseases	7,219	—	7,219
Anti-FcRn franchise—other clinical and nonclinical	7,903	11,875	(3,972)
Brepocitinib	10,517	8,755	1,762
Mosliciguat	6,184	234	5,950
Namilumab	3,491	3,331	160
RVT-2001	216	3,739	(3,523)
RVT-3101	—	18,553	(18,553)
Other development and discovery programs	9,972	10,761	(789)
Total program-specific costs	90,003	70,812	19,191
Unallocated internal costs:			
Share-based compensation	9,911	8,309	1,602
Personnel-related expenses	33,577	26,411	7,166
Other expenses	9,582	9,258	324
Total research and development expenses	$ 143,073	$ 114,790	$ 28,283

[1] Certain prior year amounts have been reclassified to conform to current year presentation.

Research and development expenses increased by $28.3 million to $143.1 million for the three months ended September 30, 2024, compared to $114.8 million for the three months ended September 30, 2023. This increase was primarily driven by increases in program-specific costs of $19.2 million, personnel-related expenses of $7.2 million, and share-based compensation of $1.6 million.

Within program-specific costs, the increase of $19.2 million was primarily driven by an increase in expense of $34.2 million related to the anti-FcRn franchise, partially offset by a decrease in expense of $18.6 million related to RVT-3101, which was sold to Roche in December 2023.

For the six months ended September 30, 2024 and 2023**,** our research and development expenses consisted of the following:

	Six Months Ended September 30,		
	2024	2023[1]	Change
		(in thousands)	
Program-specific costs:			
Anti-FcRn franchise—neurological diseases	$ 47,956	$ 16,376	$ 31,580
Anti-FcRn franchise—endocrine diseases	30,937	14,750	16,187
Anti-FcRn franchise—rheumatology diseases	7,219	—	7,219
Anti-FcRn franchise—other clinical and nonclinical	14,304	21,705	(7,401)
Brepocitinib	21,111	16,518	4,593
Mosliciguat	9,164	234	8,930
Namilumab	7,868	6,633	1,235
RVT-2001	1,875	7,561	(5,686)
RVT-3101	—	29,478	(29,478)
Other development and discovery programs	19,451	20,138	(687)
Total program-specific costs	159,885	133,393	26,492
Unallocated internal costs:			
Share-based compensation	20,443	15,726	4,717
Personnel-related expenses	65,122	56,596	8,526
Other expenses	18,130	18,491	(361)
Total research and development expenses	$ 263,580	$ 224,206	$ 39,374

[1]Certain prior year amounts have been reclassified to conform to current year presentation.

Research and development expenses increased by $39.4 million to $263.6 million for the six months ended September 30, 2024, compared to $224.2 million for the six months ended September 30, 2023. This increase was primarily driven by increases in program-specific costs of $26.5 million, personnel-related expenses of $8.5 million, and share-based compensation of $4.7 million.

Within program-specific costs, the increase of $26.5 million was primarily driven by increases in expense of $47.6 million related to the anti-FcRn franchise and $8.9 million related to mosliciguat as a result of its acquisition during the three months ended September 2023. These increases were partially offset by a decrease in expense of $29.5 million related to RVT-3101, which was sold to Roche in December 2023.

Acquired in-process research and development expenses

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	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 relating to the asset acquisition of mosliciguat completed by our wholly-owned subsidiary, Pulmovant.

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 relating to the asset acquisition of mosliciguat completed by our wholly-owned subsidiary, Pulmovant, and $12.5 million relating to the achievement of development and regulatory milestones for batoclimab.

General and administrative expenses

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
General and administrative	$ 202,881	$ 88,576	$ 114,305	$ 302,773	$ 179,858	$ 122,915

General and administrative expenses increased by $114.3 million to $202.9 million for the three months ended September 30, 2024, compared to $88.6 million for the three months ended September 30, 2023. This increase was primarily due to an increase in personnel-related expenses of $87.0 million, of which $79.1 million related to the one-time cash retention awards approved in July 2024 for each of Matthew Gline, Chief Executive Officer; Mayukh Sukhatme, President and Chief Investment Officer; and Eric Venker, President and Chief Operating Officer (the "2024 Senior Executive Compensation Program") and $6.6 million related to the special one-time cash retention bonus award granted to employees, following approval in December 2023. The increase was also driven by an increase in share-based compensation expense of $21.7 million, primarily due to the long-term equity incentive awards granted in July 2024 pursuant to the 2024 Senior Executive Compensation Program.

General and administrative expenses increased by $122.9 million to $302.8 million for the six months ended September 30, 2024, compared to $179.9 million for the six months ended September 30, 2023. This increase was primarily due to an increase in personnel-related expenses of $94.8 million, of which $79.1 million related to the one-time cash retention awards approved in July 2024 pursuant to the 2024 Senior Executive Compensation Program and $13.5 million related to the special one-time cash retention bonus award granted to employees, following approval in December 2023. The increase was also driven by an increase in share-based compensation expense of $19.8 million, primarily due to the long-term equity incentive awards granted in July 2024 pursuant to the 2024 Senior Executive Compensation Program.

Gain on sale of Telavant net assets

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Gain on sale of Telavant net assets	$ —	$ —	$ —	$ 110,387	$ —	$ 110,387

Gain on sale of Telavant net assets was approximately $110.4 million for the six months ended September 30, 2024 and resulted from the achievement of a one-time milestone achieved in June 2024. Refer to Note 5, "Recent Transactions and Developments" of our financial statements for further information regarding the milestone.

Change in fair value of investments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Change in fair value of investments	$ (48,375)	$ 45,849	$ (94,224)	$ (63,601)	$ 53,413	$ (117,014)

Change in fair value of investments was an unrealized gain of $48.4 million and an unrealized loss of $45.8 million for the three months ended September 30, 2024 and 2023, respectively. The change of $94.2 million was primarily driven by changes in the public share price of Arbutus and the change in fair value of our investment in Datavant.

Change in fair value of investments was an unrealized gain of $63.6 million and an unrealized loss of $53.4 million for the six months ended September 30, 2024 and 2023, respectively. The change of $117.0 million was primarily driven by changes in the public share price of Arbutus and the change in fair value of our investment in Datavant.

Change in fair value of liability instruments

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Change in fair value of liability instruments	$ (635)	$ 11,789	$ (12,424)	$ 515	$ 51,967	$ (51,452)

Change in fair value of liability instruments was a gain of $0.6 million and a loss of $0.5 million for the three and six months ended September 30, 2024, respectively. Change in fair value of liability instruments was not significant in either period presented.

Change in fair value of liability instruments were losses of $11.8 million and $52.0 million for the three and six months ended September 30, 2023 and primarily consisted of losses of $11.7 million and $51.7 million, respectively, 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,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Gain on deconsolidation of subsidiaries	$ —	$ (17,354)	$ 17,354	$ —	$ (17,354)	$ 17,354

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. in July 2023 and Proteovant Sciences Inc. in August 2023.

Interest income

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Interest income	$ (69,773)	$ (14,299)	$ (55,474)	$ (141,900)	$ (31,014)	$ (110,886)

Interest income increased by $55.5 million to $69.8 million for the three months ended September 30, 2024, compared to $14.3 million for the three months ended September 30, 2023. The increase is primarily due to higher cash balances in our interest-bearing cash accounts.

Interest income increased by $110.9 million to $141.9 million for the six months ended September 30, 2024, compared to $31.0 million for the six months ended September 30, 2023. The increase is primarily due to higher cash balances in our interest-bearing cash accounts and higher interest rates.

Income tax expense

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
Income tax expense	$ 12,458	$ 3,236	$ 9,222	$ 24,421	$ 4,911	$ 19,510

Income tax expense increased by $9.2 million to $12.5 million for the three months ended September 30, 2024, compared to $3.2 million for the three months ended September 30, 2023. The increase is primarily due to our earnings by legal entity in various jurisdictions, which is driven by an increase in interest income.

Income tax expense increased by $19.5 million to $24.4 million for the six months ended September 30, 2024, compared to $4.9 million for the six months ended September 30, 2023. The increase is primarily due to our earnings by legal entity in various jurisdictions, which is driven by an increase in interest income.

(Loss) income from discontinued operations, net of tax

	Three Months Ended September 30,			Six Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
		(in thousands)			*(in thousands)*	
(Loss) income from discontinued operations, net of tax	$ (43,083)	$ (86,476)	$ 43,393	$ 46,010	$ (169,094)	$ 215,104

Loss from discontinued operations, net of tax was $43.1 million and $86.5 million for the three months ended September 30, 2024 and 2023, respectively. Income (loss) from discontinued operations, net of tax was income of $46.0 million and a loss of $169.1 million for the six months ended September 30, 2024 and 2023, respectively. These amounts represent the financial results of Dermavant. Refer to Note 6, “Discontinued Operations” of our financial statements for further information.

Liquidity and Capital Resources

For the six months ended September 30, 2024 and 2023, we incurred net losses from continuing operations of $268.4 million and $489.9 million, respectively. As of September 30, 2024, we had cash, cash equivalents and marketable securities of approximately $5.4 billion and our retained earnings was $395.6 million. 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 2024, Dermavant entered into the Merger Agreement with Organon, Merger Sub, and us, solely in our capacity as the representative of the securityholders of Dermavant. Organon's acquisition of Dermavant was completed in October 2024, subsequent to quarter end.

Organon agreed to acquire Dermavant for aggregate cash consideration comprising (i) a payment of $175.0 million payable at the closing of the Dermavant Transaction, subject to certain adjustments, (ii) a $75.0 million milestone payment payable upon FDA approval of VTAMA (the "Product") for the treatment of atopic dermatitis and (iii) up to $950.0 million in additional milestone payments payable upon achievement of certain tiered net sales amounts with respect to the Product, each less than or equal to $1.0 billion. Additionally, Organon agreed to make tiered royalty payments of (x) low-to-mid single digit percentages with respect to annual net sales of the Product up to $1.0 billion and (y) 30% with respect to annual net sales of the Product above $1.0 billion. Such consideration and royalty payments are payable to all of Dermavant's equity holders, including holders of restricted stock units, options and warrants, on a pro rata basis relative to their ownership of Dermavant prior to the closing of the Dermavant Transaction (in each case, after giving effect to the liquidation preference of Dermavant's preference shares, all of which are held by us, and otherwise in accordance with the applicable terms of such securities). Under the liquidation preference of Dermavant's preference shares, we are entitled to receive 100% of the first $270.0 million of consideration paid pursuant to the Merger Agreement. We received $183.6 million in cash in October 2024 upon the closing of the Dermavant Transaction.

As contemplated by the Merger Agreement, in connection with the closing of the Dermavant Transaction, Dermavant repaid all amounts outstanding or otherwise payable (including accrued interest and all premiums and exit fees) pursuant to a senior secured credit facility (the "Credit Facility"), dated as of May 14, 2021 and amended as of May 24, 2024, by and among Dermavant, certain subsidiaries of Dermavant, XYQ Luxco S.A.R.L. and U.S. Bank Trust Company, National Association, and terminated the Credit Facility in accordance with its terms.

Following the closing of the Dermavant Transaction, all rights and obligations under each of (A) the Revenue Interest Purchase and Sale Agreement, dated as of May 14, 2021 and amended as of May 24, 2024, by and among Dermavant, Dermavant Sciences GmbH, XYQ Luxco S.A.R.L., NovaQuest Co-Investment Funds XVII, L.P., MAM Tapir Lender, LLC and U.S. Bank Trust Company, National Association and (B) the Funding Agreement, dated as of July 10, 2018 and amended as of May 24, 2024, by and among Dermavant, Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P., were retained by Dermavant and its subsidiaries, which became indirect wholly owned subsidiaries of Organon. Refer to Note 6, "Discontinued Operations" of our financial statements for further information.

Share Repurchase Program

Our board of directors authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses). The repurchase program is funded by available cash and cash equivalents on hand and does not have an expiration date. In April 2024, pursuant to the share repurchase program, we entered into a share repurchase agreement with Sumitomo Pharma Co., Ltd. ("Sumitomo") and repurchased all 71,251,083 common shares held by Sumitomo at a purchase price per share of $9.10, for an aggregate purchase price of approximately $648.4 million. Repurchases of an additional 9,023,658 shares were made in open market transactions under the share repurchase program in the three months ended September 30, 2024 for an aggregate purchase price of approximately $106.1 million.

Liquidity Requirements

Our short-term and long-term liquidity requirements as of September 30, 2024 included:

- obligations under our leases. Refer to Note 13, "Leases" in our Annual Report on Form 10-K for the year ended March 31, 2024 for further information regarding our lease commitments. In September 2024, our subsidiary, Roivant Sciences, Inc. ("RSI"), entered into a lease agreement (the "RSI Lease Agreement") with One Penn Plaza LLC for office space in New York, NY to serve as the future U.S. corporate headquarters of RSI. The RSI Lease Agreement has an expected commencement date on or after December 14, 2024 and will expire on or after July 31, 2041 with an option to extend. The approximate future minimum obligation under this lease is $115.0 million, and RSI is eligible to receive a credit of $1.8 million. As of September 30, 2024, a lease commencement date in accordance with ASC 842, Leases, had not occurred. As such, no lease liability or right-of-use asset relating to the RSI Lease Agreement has been recorded.

- certain commitments to Samsung Biologics Co., Ltd. ("Samsung") pursuant to a Product Service Agreement ("PSA") entered between Immunovant and Samsung pursuant to which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale, if approved, and perform other manufacturing-related services with respect to batoclimab. Upon execution of the PSA, Immunovant committed to purchase process performance qualification batches of batoclimab and pre-approval inspection batches of batoclimab which may be used for regulatory submissions and, pending regulatory approval, commercial sale. In addition, Immunovant has a minimum obligation to purchase further batches of batoclimab in the four-year period of 2026 through 2029. As of September 30, 2024, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $43.6 million.

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

We have entered into commitments 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 the 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. We expect to enter into additional asset acquisition and license agreements in the future, which may require upfront payments and long-term commitments of capital resources.

We enter into agreements with contract service providers to assist in the performance of our research and development activities. Expenditures to contract research organizations and contract manufacturing organizations represent significant costs in the clinical development of our product candidates. Subject to required notice periods and certain obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. We expect 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.

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. 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 any drug candidates for which we may obtain regulatory approval; and

- operate as a public company.

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

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

Finally, as part of our ongoing business strategy we regularly evaluate new acquisition and in-licensing opportunities, as well as our capital structure. We may from time to time use our existing cash to fund such opportunities or to retire outstanding debt obligations or to return capital to shareholders though share repurchases or the issuance of cash dividends on our common shares to optimize our capital structure. See "Risk Factors—Risks Related to Our Business and Industry—We face risks associated with strategic transactions and partnerships and we may not realize the expected benefits of those strategic transactions and partnerships." for more information.

Cash Flows

The following table sets forth a summary of our cash flows for the six months ended September 30, 2024 and 2023:

	Six Months Ended September 30,	
	2024	**2023**
	(in thousands)	
Net cash used in operating activities	$ (459,635)	$ (446,359)
Net cash used in investing activities	$ (3,294,559)	$ (36,346)
Net cash (used in) provided by financing activities	$ (769,690)	$ 215,349

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, 2024, cash used in operating activities increased by $13.3 million to $459.6 million compared to $446.4 million for the six months ended September 30, 2023.

Investing Activities

For the six months ended September 30, 2024 and 2023, cash used in investing activities increased by approximately $3.3 billion to approximately $3.3 billion compared to $36.3 million for the six months ended September 30, 2023 as a result of purchases of marketable securities during the six months ended September 30, 2024.

Financing Activities

For the six months ended September 30, 2024 and 2023, cash flow from financing activities changed by $985.0 million to net cash used in financing activities of $769.7 million from net cash provided by financing activities of $215.3 million for the six months ended September 30, 2023. During the six months ended September 30, 2024, net cash used in financing activities was primarily due to the repurchase of $754.4 million of our common shares during the six months ended September 30, 2024. 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.

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, 2024 in our Form 10-K.

Recent Accounting Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our unaudited condensed consolidated financial statements, refer to Note 2, "Summary of Significant Accounting Policies" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As of September 30, 2024, we had cash, cash equivalents, restricted cash and marketable securities of approximately $5.4 billion. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of our account portfolio, an immediate hypothetical 10% change in interest rates would not have a material effect on our liquidity.

Foreign Currency Exchange Rate Risk

Our employees and our operations are currently primarily located in the U.S., and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we are exposed to fluctuations in foreign currency exchange rate risk as a result of entering into transactions denominated in currencies other than U.S. dollars as we have contracted with and may continue to contract with foreign vendors and counterparties. We believe an immediate hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our liquidity or our condensed consolidated financial statements.

Equity Price Risk

As of September 30, 2024, we were exposed to price risk on equity securities included in our portfolio of investments, the most significant of which were our investments in Arbutus and Datavant. Our investments in Arbutus and Datavant are measured at fair value with any changes in fair value recognized in our statements of operations, which therefore may increase the volatility of our earnings. A hypothetical 20% increase or decrease in our investments in Arbutus and Datavant would have increased or decreased their fair value as of September 30, 2024 by approximately $62 million.

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, 2024, 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, 2024 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, 2024 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.

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. References to our "product candidates" include our current and any future products or product candidates. Approval from the U.S. Food and Drug Administration ("FDA") or other applicable international regulatory authority is required before a product or product candidate may be marketed and sold in the relevant jurisdiction.

Risks Related to Our Business and Industry

Risks Related to Our Strategy and Financial Position

Our relatively limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development and commercialization may make it difficult for us to execute on our business model and for you to assess our future viability.

We are a clinical-stage biopharmaceutical and healthcare technology company with a relatively 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, which we refer to as "Vants." Following the acquisition of our subsidiary Dermavant by Organon (the "Dermavant Transaction"), completed in October 2024, we no longer have a commercial-stage product and we do not expect to generate product revenues from the commercial sale of our product candidates for the foreseeable future.

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

- successfully complete ongoing clinical trials and obtain regulatory approvals for our product candidates;
- identify new acquisition or in-licensing opportunities;
- realize the benefits of our strategic partnerships and other collaborations, including the Dermavant Transaction;
- launch commercial sales of our product candidates following regulatory approvals, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- attract and retain experienced management teams and operational personnel to support our ongoing clinical development efforts, including at newly formed Vants, and successfully prepare for the commercialization of our product candidates following regulatory approvals;
- initiate and maintain relationships with third-party suppliers and manufacturers and have commercial quantities of product candidates, following regulatory approvals, manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- set acceptable prices for our product candidates following regulatory approvals and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of product candidates following regulatory approvals in the medical community and with third-party payors and consumers;

- raise additional funds when needed and on terms acceptable to us;
- successfully grow our healthcare technology Vants and market the products and services offered by those Vants;
- successfully identify new product candidates through our discovery efforts and advance those product candidates into preclinical studies and clinical trials; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict when and if our 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 revenues from the sale of those product candidates following regulatory approvals or achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities to perform studies or clinical trials in addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval in the U.S. or another jurisdiction, or if there are any delays in any of our clinical trials or the development of our product candidates. Our inability to successfully execute on the objectives described herein would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may never achieve sustained profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Following the Dermavant Transaction we do not have any product candidates that have received marketing approval anywhere in the world and we do not expect to generate product revenues from the commercial sale of our product candidates for the foreseeable future. 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, 2024, we had cash, cash equivalents and marketable securities of approximately $5.4 billion and retained earnings of approximately $395.6 million.

We may never be able to successfully develop, achieve regulatory approvals for or commercialize our product candidates. Even if approved, our product candidates may not generate meaningful product revenues or enable us to achieve or maintain profitability. It is therefore possible that we will incur substantial operating losses for the foreseeable future. Our ability to generate meaningful product revenues and achieve and sustain profitability depends on our ability to complete the development of our product candidates, obtain necessary regulatory approvals for our product candidates and manufacture and successfully market our product candidates alone or in collaboration with others. Revenues from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we have or may gain regulatory approval, the accepted price for the product candidate, the ability to obtain reimbursement at any price, the strength and term of patent exclusivity for the product candidate and the overall competitive landscape. Even if we achieve profitability from product revenues in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve and sustain profitability could depress the market value of our company and impair our ability to raise capital, expand our business and pipeline and market any product candidates following regulatory approval.

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

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

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

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

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

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

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

We face risks associated with the Vant structure.

Our product candidates are developed at our Vants, which operate similarly to independent biopharmaceutical companies with their own management teams and equity incentive structures. While we believe that there are significant competitive advantages to this structure, as compared to traditional pharmaceutical companies or smaller biopharma companies, the Vant structure also poses certain risks for our business.

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

In addition, a single or limited number of the Vants may, now or in the future, comprise a large proportion of our value. Similarly, in the future a large proportion of our consolidated revenues could be derived from one or a small number of Vants. Any adverse development at a key 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 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 certain of our Vants, including our publicly traded subsidiary, Immunovant. By virtue of Immunovant being a publicly traded company, our operational control of Immunovant is also limited in certain respects and certain transactions between us and Immunovant may require the prior approval of a special committee of independent directors, which we do not control. This structure could result in delays in certain financing or other transactions at Immunovant, or prevent us from taking certain actions with respect to Immunovant that we think are in our best interests as a majority shareholder of Immunovant. In addition, certain of our Vants have issued equity securities senior to our ownership interests, which dilutes our economic interest in the Vants and can in certain cases limit our operational control of the Vant.

Our Vants also have equity incentive plans, which can result in the dilution of our ownership interest in the Vant as the awards issued under those plans vest and are exercised. The vesting and exercise of incentive equity awards at the Vants, as well as future capital needs at the Vants – which may be financed through senior debt or equity securities or common equity – may further dilute or subordinate our ownership and economic interests in the Vants or reduce our operational control of the Vants. In addition, recipients of Vant equity awards may have economic alignment with a Vant that incentivizes them to act in ways that prioritize the success of a Vant over the success of the Company as a whole, which could adversely impact our consolidated business, financial condition, results of operations or prospects. For more information on our ownership of our Vants, see "Management's Discussion and Analysis of Financial Condition and Results of Operations–Overview."

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

We face risks associated with potential future payments we may owe in connection with our product candidates.

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

We face risks associated with strategic transactions and partnerships and we may not realize the expected benefits of those strategic transactions and partnerships.

From time to time, we may consider strategic transactions, including acquisitions or divestitures of companies, asset purchases or sales and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spinoffs, strategic partnerships, joint ventures, collaborations, restructurings, divestitures, business combinations and investments. We face certain risks in connection with these transactions and, even if consummated, may not realize the expected benefits of those transactions.

For example, in October 2024 we completed the Dermavant Transaction, the consideration for which consisted of an upfront payment of $183.6 million and a $75 million milestone payment upon FDA approval of VTAMA for the treatment of atopic dermatitis. In addition, at closing, all former Dermavant equity holders, including Roivant, received the right to receive their pro rata portion of (i) milestone payments of up to $950 million for the achievements of certain tiered net sales amounts with respect to VTAMA, each less than or equal to $1 billion and (ii) and tiered royalties of (x) low-to-mid single digit percentages with respect to annual net sales of VTAMA up to $1 billion and (y) 30% with respect to annual net sales of VTAMA above $1 billion. There can be no assurance that we will receive any of the future milestone or royalty payments owed in connection with the Dermavant Transaction, or that the proceeds from the Dermavant Transaction will exceed the profits that we could have generated if we had continued to own and operate Dermavant as one of our Vants. For more information on the Dermavant Transaction, please refer to Note 6—Discontinued Operations to Roivant's unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Any future transactions could also 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 may never be successful and may require significant time and attention of our management, as well as significant costs, whether or not successfully consummated.

In addition, the integration or separation of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the transaction. For any alliances or joint ventures that we enter into in the biopharmaceutical industry, we may encounter numerous difficulties in discovering, developing, manufacturing and marketing any new products or product candidates related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. Divestiture transactions such as the Dermavant Transaction may adversely impact the price of our common shares, to the extent investors believe the value of the consideration received in the transaction is not equivalent to the value of the asset or program divested. Accordingly, there can be no assurance that transactions of the nature described above will be undertaken or successfully completed, and that any transaction we do complete will not have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As of September 30, 2024, we had cash, cash equivalents and marketable securities of approximately $5.4 billion. Our management team has broad discretion in respect of use of our cash, cash equivalents and marketable securities. We may use all or a portion of such proceeds for one or more strategic transactions, including acquisitions of companies, asset purchases or sales or in-licensing of intellectual property, products or product candidates or technologies, as described above. We may not be able to find a suitable strategic transaction that we deem sufficiently attractive to pursue, and may not be able to complete a strategic transaction in the future. Our ability to complete a strategic transaction may be negatively impacted by general market conditions, volatility in the capital markets and the other risks described herein.

We may also decide to return capital to shareholders through one or a combination of public or private share repurchases, or the issuance of cash dividends on our common shares. As previously disclosed, our board of directors has authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses) (the "2024 Repurchase Program"). In April 2024, pursuant to the 2024 Share Repurchase Program, the Company entered into a share repurchase agreement with Sumitomo Pharma Co., Ltd. ("Sumitomo") and repurchased all 71,251,083 common shares held by Sumitomo at a purchase price per share of $9.10, for an aggregate purchase price of approximately $648.4 million. Repurchases of an additional 9,023,658 shares were made in open market transactions under the 2024 Share Repurchase Program in the three months ended September 30, 2024 for an aggregate purchase price of approximately $106.1 million (excluding 960,692 common shares which were repurchased on September 30, 2024 with a settlement date of October 1, 2024).

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

The amount of cash available to return to shareholders, if any, can vary significantly from period to period for a number of reasons, including, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. The returns of capital to shareholders may change in form, amount, value and frequency from time to time, and we cannot guarantee that any such future returns of capital will take place. The trading price of our common shares may decline, possibly materially, if we are unable to meet investor expectations with respect to the timing and total amount of future capital returns to shareholders. There is no guarantee that our significant balance of cash, cash equivalents and marketable securities will be used to increase our operating results, return capital to shareholders or enhance the value of our common shares.

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

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

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

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

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

- the time and costs necessary to complete our ongoing, planned and future clinical trials for our product candidates;
- the time and costs necessary to pursue regulatory approvals for our product candidates;
- the costs associated with future acquisitions or in-licensing transactions;
- the approval, progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner for our ongoing and planned clinical trials and potential future clinical trials for our product candidates;
- the costs associated with our ongoing, planned and future preclinical studies and other drug discovery activities;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations ("CMOs");
- the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our product candidates;
- the timing and amount of proceeds realized from the contingent future payments owed to us in connection with the Dermavant Transaction;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, including current and future patent infringement actions brought against third parties, for our product candidates;
- the cost of pursuing and defending potential intellectual property disputes, including patent infringement actions with third parties, relating to our product candidates; and
- our ability to hire, attract and retain qualified personnel.

In the event that we require additional financing, we cannot be certain that additional capital will be available to us or the Vants on acceptable terms, or at all. If we or the Vants are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our in-licensing and acquisition, discovery, development, commercialization and marketing activities. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our business. Because of the numerous risks and uncertainties associated with our business, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and future product development programs and discovery efforts. Moreover, risks associated with broader market conditions, including high levels of inflation, heightened interest rates and increasing market and banking sector instability and volatility, all of which have been observed in recent periods, may further adversely impact our ability to obtain financing on acceptable terms or at all.

In the future, we may require significant additional capital to continue our operations, pursue business opportunities or strategic transactions, or respond to challenges, competition or unforeseen circumstances. Until such time, if ever, that we can generate substantial revenues, we may finance future cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations at Roivant and the Vants. To the extent that we raise additional capital by issuing equity securities at Roivant or the Vants, our existing shareholders' ownership, or our ownership in the Vants, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of our shareholders. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our 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 product candidates 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 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 product candidates, assumptions related to adoption of a particular therapy, incidence and prevalence of an indication, use of a product candidate versus competitor therapies and size of the addressable patient populations. Some or all of these assumptions may be incorrect due to errors or mistaken assumptions in our analysis or the inherent uncertainties in the drug development process, among other reasons. We cannot accurately predict whether, following regulatory approvals, our product candidates will achieve significant market acceptance in line with these assumptions or whether there will be a market for our product candidates that reaches the anticipated size. If any of these assumptions are incorrect or overstated, our results and future prospects will be materially and adversely affected.

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

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

Risks Related to the Development of Our 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 ("U.K."), 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 U.K. may be submitted, a Clinical Trial Application ("CTA"). We cannot provide any assurance that we will submit an IND, NDA, CTA or other similar application for regulatory approval for our product candidates within projected timeframes or whether any such application will be accepted for review or ultimately approved by the relevant regulatory authorities.

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

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

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

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

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

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

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

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

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

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

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

Patient enrollment and retention in clinical trials depends on many factors, 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, limited trial site capacity and staffing as a result of healthcare worker shortages, 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 product candidates, including IMVT-1402 and batoclimab, which target certain autoimmune indications, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. In addition, for certain of our early-stage development programs, there may be a limited number of sites where it is feasible to run clinical trials, making such programs particularly susceptible to delays caused by issues at those sites.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our 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 product candidates or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior preclinical studies and earlier clinical trials. For example, we cannot assure you that the reductions in IgG antibodies and favorable analyte profile observed in our Phase 1 trial of IMVT-1402 will be observed in future clinical trials, including pivotal trials necessary for regulatory approvals, or that such reductions in IgG antibodies will result in clinical benefit that is sufficient to demonstrate that the efficacy endpoints of the study are met. 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 product candidates may not be predictive of the results of later-stage clinical trials. 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 product candidates following regulatory approval, and generate product revenues. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidates. The FDA and other regulatory authorities, including the European Commission, the EMA and the MHRA, have substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of product candidates under development result in the submission of an NDA or other similar application to the FDA and other comparable non-U.S. regulatory authorities and even fewer are approved for commercialization.

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

From time to time, and in some countries, in line with the applicable requirements set out in legislation and guidance, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data. For example, we previously disclosed 24-week data from our NEPTUNE trial of brepocitinib in non-anterior non-infectious uveitis ("NIU"), results from the initial cohort of patients in our Phase 2 trial of batoclimab in Graves' disease and initial human data from our Phase 1 trial of IMVT-1402. These results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously reported. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares.

Further, other parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of a particular product 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 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 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 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 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 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 candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of our 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 product candidates. Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our preclinical studies, clinical trials, research and development activities and, following approval, commercialization. Any significant delay in the supply of a 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 product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involve committing substantial financial resources to product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals were recently enacted or are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the U.S. on foreign supply chains and manufacturing. While we are still assessing these developments, they could impact our selection and utilization of CMOs, vendors and other suppliers and could have a material adverse impact on our business, financial condition and results of operations.

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

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

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

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

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

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the U.S. These regulations govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our 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 product candidates and sanctions being imposed on us, including clinical holds, import alerts, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical supplies of our product candidates or, following approval, commercial supplies for those product candidates.

We and/or our CMOs must supply all necessary documentation in support of an NDA or similar regulatory application on a timely basis, and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our 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 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 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 candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Accordingly, switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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

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

Our 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 U.K. 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 conduct clinical trials with our product candidates or meet potential future market demand for our product candidates following regulatory approval.

Risks Related to Regulatory Approval and Commercialization of Our Product Candidates

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

We cannot commercialize a product candidate 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. Following the completion of the Dermavant Transaction in October 2024, we no longer have any approved products in the U.S. or any other jurisdiction and there can be no assurance that we will be successful in obtaining regulatory approval in the U.S. and other jurisdictions for any of our product candidates. In addition, we cannot be certain that any product candidates that receive regulatory approval will be successfully commercialized.

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

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

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

- the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of clinical trials, including the design of proposed preclinical and early clinical trials of any future product candidates;
- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact the clinical trials and ability to obtain marketing approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical, preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, preclinical studies or clinical trials or may require additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites, including in situations where the authorities deem that the data was not generated in compliance with GCP, ethical standards or applicable data protection laws;
- if an NDA, BLA or a similar application is referred for review by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authorities, as the case may be, require, as a condition of approval, additional nonclinical, preclinical studies or clinical trials, limitations on approved labelling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy ("REMS") drug safety program or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or patient registries for product candidates;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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

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

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

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

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

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

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

Adverse events caused by or associated with our 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 future product candidates that are approved cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, revoke, suspend, vary, or limit their approval of the product candidate or require a REMS (or equivalent outside the U.S.) to impose restrictions on its distribution or other risk management measures;
- regulatory authorities may request or require that we recall a product candidate;
- additional restrictions being imposed on the distribution, marketing or manufacturing processes of our product candidates 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 candidate;
- regulatory authorities may require the addition of labelling statements, such as warnings or contraindications, require other labelling changes of a product candidate or require field alerts or other communications to physicians, pharmacies or the public;
- we may be required to change the way a product candidate is administered or distributed, conduct additional clinical trials, change the labelling of a product candidate 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 candidate;
- reimbursement may not be available for a product candidate;

- we may elect to discontinue the sale of a product candidate;
- our product candidates may become less competitive; and
- our reputation may suffer.

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

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

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

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

Seeking regulatory approval outside of the U.S. could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The regulatory approval process outside of the U.S. may include all of the risks associated with obtaining FDA approval. We do not have any 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 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.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for manufacturing processes, post-approval clinical data, 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 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 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 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 U.K. we will be prohibited from promoting prescription-only medicinal products to individuals who are not healthcare professionals. Violations of the FDCA in the U.S. and other comparable laws and regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non-U.S. regulatory agencies alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in other jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our 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 product candidates;
- restrictions on the labelling or marketing of such product candidates, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the U.S.);
- Warning or Untitled Letters or similar communications from other relevant regulatory authorities;
- withdrawal of the product candidates from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- seizure of our 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 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 product candidates, which may result in difficulty in successfully launching product candidates following regulatory approval and the loss of potential future sales, which could have an adverse effect on our business, financial condition, and results of operations.

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

We have sought, or may in the future seek, Breakthrough Therapy Designation, Fast Track Designation or Orphan Drug Designation for certain of our product candidates. For example, in July 2021, Immunovant was granted orphan drug designation in the U.S. by the FDA for batoclimab for the treatment of MG and, in August 2022, it received orphan drug designation from the European Commission for batoclimab for the treatment of MG. Immunovant plans to seek orphan drug designation from the FDA for IMVT-1402 where there is a medically plausible basis for IMVT-1402's use. Immunovant may also seek orphan drug designation for IMVT-1402 for the treatment of other indications in the E.U. In addition, in September 2024, Priovant announced that brepocitinib has been granted Fast Track Designation from FDA for NIU. We may seek similar designations for other of our 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 and that the FDA is otherwise exercising its new authorities. At this time, it is not clear what impact, if any, these developments may have on our business, financial condition results of operations or prospects.

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

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

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

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

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

From January 1, 2021, a separate process for orphan drug designation has applied in Great Britain. There is no pre-marketing authorization orphan designation step required (as there is in the EEA), and the application for orphan designation will be reviewed by the MHRA at the time of the marketing authorization application. The criteria are the same as in the EEA, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain). Orphan exclusivity granted to a centralized marketing authorization will also apply in Northern Ireland (although this may change if the Windsor Agreement is implemented).

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 and "normal" data and market exclusivities may be modulated or shortened if we submit an application for marketing authorization for an orphan medicinal product after the start of application of the new 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 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 product candidates, once regulatory approval has been received, 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 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 candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

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

Any future commercialization efforts will be dependent on sales, marketing and distribution capabilities, including agreements with third parties to sell, market and distribute our product candidates.

In order to effectively market our product candidates following regulatory approval, we must successfully employ our sales, distribution, marketing and related capabilities or make arrangements with third parties to perform these services. Our Vants with product candidates in late-stage clinical development, including Immunovant and Priovant, do not currently have a sales, marketing and distribution infrastructure, and would expect to build such a function, or make arrangements with third parties to perform these services in connection with the commercialization of one of their product candidates following regulatory approval.

There are risks involved with both establishing and maintaining internal commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product 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. The costs associated with a sales, marketing and distribution infrastructure may exceed the net revenues we are able to generate from the sale of a product candidate following regulatory approval.

Factors that may inhibit our efforts to commercialize a product candidate, if approved, 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 or the Vants are unable to build an internal sales force or negotiate a collaborative relationship for the commercialization of a product candidate following regulatory approval, it could result in a delay to, or reduce the effectiveness of, our commercialization efforts. This could adversely impact the product revenues generated from a product candidate following regulatory approval.

If we decide to fund commercialization activities ourselves, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring a product candidate to market or generate product revenues. 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 a 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 revenues, including net revenues, may be lower than if we were to market and sell a product candidate through an internal sales force. 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 product candidates effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates following regulatory approvals, which could have an adverse effect on our business, financial condition, and results of operations.

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

Our business operations and current and potential future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, charitable organizations, customers, and others, expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates following regulatory approvals. 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. The False Claims Act provides for suit by the federal government or private parties (*qui tam* relator) and when an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties 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 personally identifiable health information in connection with providing a service for or on behalf of the covered entity;

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

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

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

- 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;

- U.S. federal drug price reporting and government contracting statutes and regulations, the violation of which can lead to civil penalties, debarment, and/or enforcement under the federal False Claims Act, and certain local and state laws that require disclosures to state agencies or boards and/or commercial purchasers, for example, with respect to certain price increases, 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 or state healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena, civil investigative demand or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

The U.S. and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities for our product candidates, affect our ability to profitably sell our product candidates following regulatory approval and prevent or delay marketing approval of our 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.

The U.S. government enacted the Inflation Reduction Act of 2022 (the "IRA"), the implementation and scope of which is subject to change through ongoing and future regulatory processes and rulemaking, and which could result in additional rebate payments for certain products, adversely affect the pricing of healthcare products and services in the U.S. and implement price limitations or otherwise restrict the amount of reimbursement available from governmental agencies or third-party payors. In addition, the IRA includes provisions that generally require manufacturers of Medicare Part B and Part D rebatable drugs to pay inflation rebates to the Medicare program if pricing metrics associated with their products increase faster than the rate of inflation. The impact of the IRA on research and development, the pharmaceutical supply chain and other aspects of our business and industry remains uncertain and difficult to predict.

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

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

There has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Additionally, U.S. regulators continue to pursue policies designed to lower drug costs for federal programs and patients. In May 2019, the CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. This rulemaking also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. However, Congress has adopted various delays on the implementation or enforcement of the rule, including a postponement until January 2032 under the IRA.

On December 31, 2020, CMS enacted a final rule that, among other things, expanded the scope of drug products that may be considered "line extensions" subject to inflationary rebates under the Medicaid Drug Rebate Program. On September 26, 2024, CMS published a Medicaid Drug Rebate Program final rule, which, among other things, amends the definitions of a "covered outpatient drug," adds regulations and penalties for drug product misclassifications, including failure to report pricing and product information in a timely manner, and limits the period for manufacturers to initiate disputes concerning state-invoiced utilization data. These changes generally take effect in November 2024 and could significantly increase manufacturer rebate liability, 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 U.K., some of which may materialize in the near term, are aimed at increasing accessibility and affordability of medicinal products, as well as at increased cooperation between the EU Member States. Such initiatives may further impact the price and reimbursement status of our products in the future.

There have been, and likely will continue to be, legislative and regulatory proposals at the national and state levels in jurisdictions around the world directed at containing or lowering the cost of healthcare, including prescription drugs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability through product revenue or commercialize our product candidates following regulatory approval. Such reforms could have an adverse effect on anticipated revenue from our product candidates following regulatory approval 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 product candidates following regulatory approval;
- our ability to receive or set a price that we believe is fair for our product candidates following regulatory approval;
- our ability to generate revenue and achieve sustained profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

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

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

Market acceptance and sales of our product candidates following regulatory approval will depend in part on the extent to which coverage and adequate reimbursement for these product candidates will be available from third-party payors, including government health administration authorities and private health insurers. The pricing and reimbursement of our product candidates following regulatory approval must be adequate to support the costs associated with commercialization efforts. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates following regulatory approval, will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our 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 product candidates following regulatory approval. There is no assurance that our product candidates will achieve adequate coverage and reimbursement levels.

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

The process for determining whether a third-party payor will provide coverage for a drug may be separate from the process for setting the price or for establishing the reimbursement rate that such a payor will pay. 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 drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular drugs. 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 candidate following regulatory approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidate for which we are able to obtain regulatory approval.

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

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates following regulatory approval. 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 product candidates following regulatory approval. 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 U.K. where a key consideration is the affordability of drugs for treatment of patients under the National Health Service. In the U.K. there is also a budget cap on branded health service medicines, and a new voluntary pricing scheme has been introduced that increases the level of rebate payment that a company is required to make to the National Health Service to take account of any spend on branded products that is above the agreed cap, and also imposes different payment rates for newer or older medicines. A consultation on the parallel statutory scheme, which applies to companies that are not members of the voluntary scheme, has recently been concluded and once the new legislation is finalized is also likely to lead to higher rebates than previously. In markets outside of the U.S., EU and U.K., 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 successfully commercialize our product candidates following regulatory approval.

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 expect to face competition in the U.S. for our product candidates from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the U.S., the Medicare Modernization Act ("MMA") contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent implementation of the rule. The court dismissed the case in February 2023. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC"), for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. Several states have enacted laws intended to support importation processes and have submitted importation program proposals to FDA. On January 5, 2024, FDA authorized Florida's importation program for the importation of certain prescription drugs from Canada into Florida; however, the state must file Pre-Import Requests for specific drug products that FDA must grant before any importation may take place. In response, Health Canada issued a statement on January 8, 2024 making clear that it is ready to take immediate action to help safeguard the Canadian drug supply if necessary. If implemented in Florida or elsewhere, importation of drugs from Canada may materially and adversely affect the price we receive for our product candidates following regulatory approval. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass other legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for our product candidates following regulatory approval and adversely affect our future revenues and prospects for profitability.

Other Risks Related to Our Business and Industry

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

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

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

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

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

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

Many of the other pharmaceutical and healthcare technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop our 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 product candidates globally. Doing business internationally involves a number of risks, including but not limited to:

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

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

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

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

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve certain regulatory approvals before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize our product candidates following regulatory approval 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. 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 product candidates for the treatment of the indications that we are also pursuing. Examples of such competing products include, but are not limited to:

- VYVGART (efgartigimod alfa-fcab) and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), neonatal Fc receptor blockers, potential competitors to IMVT-1402 and batoclimab;
- Nipocalimab and RYSTIGGO (rozanolixizumab-noli), anti-FcRn antibodies, potential competitors to IMVT-1402 and batoclimab;
- TEPEZZA (teprotumumab-trbw), an insulin-like growth factor-1 receptor inhibitor, a potential competitor to batoclimab; and
- Dazukibart, an interferon beta (IFN-beta) inhibitor, a potential competitor to brepocitinib.

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

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than our 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 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 product candidates uneconomical or obsolete and we may not be successful in marketing our 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 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 product candidates following regulatory approval.

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 product candidates. Currently and in the coming years, there may be an increased risk of cybersecurity attacks due to the ongoing Russia-Ukraine conflict, including cybersecurity attacks perpetrated by Russia or others at its direction in response to economic sanctions and other actions taken against Russia as a result of the invasion. Any increase in such attacks on us or our third-party vendors or other systems could adversely affect our network systems or other operations.

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

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

We are subject to stringent privacy, data protection and information security laws, regulations, policies and contractual obligations related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adverse effects to our business.

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

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

There are numerous U.S. federal and state laws and regulations related to the privacy, data protection and security of personal information. At the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards for "covered entities" (group health plans and most healthcare providers) that limit the use and disclosure of individually identifiable health information those entities and their service providers receive or create ("protected health information"), and require the implementation of administrative, physical and technological safeguards to protect the security, confidentiality, integrity and availability of electronic protected health information. While we generally are not subject to the HIPAA privacy or security regulations, we do business with various entities (including clinical trial investigators) that are subject to 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 considering, and many U.S. states have enacted, legislation to regulate the collection, use, and disclosure of personal health information more broadly than the HIPAA privacy and security regulations. Such legislation requires us to invest in compliance resources and creates liability risks for us.

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 consistent with consumer expectations and such companies' 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 risk of such an action is difficult to quantify and to mitigate.

As noted, an increasing number of U.S. states in which we operate have laws that protect the privacy and security of personal information. These state laws vary in scope and substance, 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 to maintain reasonable security measures to protect such information. The CMIA authorizes administrative fines and civil penalties of up to $25,000 for willful violations and up to $250,000 if the violation is for purposes of financial gain, as well as criminal fines. Washington State's My Health My Data Act, and a similar Nevada law, both of which became effective on March 31, 2024, generally require consent for the collection and use of personal health information, as well as a separate consent for sharing 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.

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

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

Outside of the U.S., laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in EEA, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on controllers, including *inter alia*: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with data protection rights of data subjects; and (iv) reporting of certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible). The GDPR also prohibits the transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. The EU-US Privacy Shield was such a transfer mechanism put in place by the EU and the U.S., but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union ("CJEU"). A replacement of the Privacy Shield – the EU-U.S. Data Privacy Framework ("DPF") was since developed. In July 2023, the U.S. and EU implemented the DPF. Companies can now use this new mechanism to transfer personal data from the EU to the U.S. and from Switzerland to the U.S., following the national implementation in Switzerland. The U.K. Extension to the EU-U.S. Data Privacy Framework ("Data Bridge") entered into force on October 12, 2023, allowing certifying entities to transfer personal data from the U.K. to the U.S. At the moment, it is unclear whether the anticipated legal challenges against the DPF, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful.

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

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

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable in the United Kingdom. However, this ended on December 31, 2020. On December 30, 2020, the United Kingdom and European Union signed the Trade and Cooperation Agreement which includes an agreement on free trade between the two parties, although provides minimal provisions on medicinal products. Since this time, Great Britain has operated a separate regulatory regime for medicinal products, although Northern Ireland continues to follow EU law. Further, on March 24, 2023, an agreement was reached by the U.K. and EU (the "Windsor Agreement"), relating to post-Brexit trade issues in Northern Ireland, which will apply from January 1, 2025. This seeks to simplify the supply of medicines between Great Britain and Northern Ireland and will mean the EU legislation will not apply in all cases in Northern Ireland. Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorizations, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as the U.K. legislation now has the potential to diverge from EU legislation. This continues to impact regulatory requirements for medicinal products and devices in the United Kingdom. The MHRA has published detailed guidance for industry and organizations on the position in the United Kingdom, and continues to update this as the United Kingdom's regulatory position on medicinal products and medical devices evolves. There are also a number of ongoing consultations on the future legislation in the U.K.

Further, as of January 1, 2021, and the expiry of transitional arrangements agreed to between the U.K. and the EU (*i.e.*, following the U.K.'s exit from the EU), data processing in the U.K. is governed by a U.K. version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the U.K., on June 28, 2021 the European Commission issued an adequacy decision in respect of the U.K.'s data protection framework, enabling data transfers from EU member states to the U.K. to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, this adequacy decisions will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or unilaterally revoked in the interim at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data. In March 2024, the British Government published the Data Protection and Digital Information (No. 2) Bill intended to create a more business-friendly regime in the U.K. through changes to the existing legislation. At this stage it is unclear whether and when this legislation will be adopted and whether such legislative reforms could potentially lead the European Commission not to extend or to revoke the U.K. adequacy decision.

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

Data privacy remains an evolving landscape at both the domestic and international level, with new laws and regulations frequently being adopted and coming into effect. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our current practices. Significant resources are needed to understand and comply with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties, including government-imposed fines or orders requiring that we change our practices or unwind certain lines of business, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even absent any findings that we have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

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

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

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

Potential product liability claims against us could cause us to incur substantial liabilities, delay our planned or ongoing clinical trials and limit commercialization of our product candidates following regulatory approval.

We face risks associated with product liability claims related to the use of our product candidates in clinical trials, future sales of our product candidates following regulatory approval or historical sales of approved products such as VTAMA. 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 prior products or prior, current and future 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 any future product candidates 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 product candidates following regulatory approval; 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 insurance coverage which extends to liabilities arising from our product candidates; 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 those 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 product candidates following regulatory approval.

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, product candidates and the diseases our product candidates 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 U.K. 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 U.K.

The use of AI could expose us to liability or adversely affect our business.

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

In addition, regulation of AI is rapidly evolving worldwide as legislators and regulators are increasingly focused on these powerful emerging technologies. The technologies underlying AI and its uses are subject to a variety of laws, including intellectual property, privacy, data protection and cybersecurity, consumer protection, competition, and equal opportunity laws, and are expected to be subject to increased regulation and new laws or new applications of existing laws. AI is the subject of ongoing review by various U.S. governmental and regulatory agencies, and various U.S. states and other foreign jurisdictions are applying, or are considering applying, their platform moderation, cybersecurity, and data protection laws to AI or are considering general legal frameworks for AI. For example, in August 2024, the EU Artificial Intelligence Act (the "EU AI Act"), which establishes broad obligations for the development and use of AI-based technologies in the EU based on their potential risks and level of impact, came into force. The EU AI Act includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, accuracy, general purpose AI and foundation models, and provides for fines of up to the greater of €35 million or 7% of worldwide annual turnover for violations. We may not be able to anticipate how to respond to these rapidly evolving frameworks, and we may need to expend resources to adjust our offerings in certain jurisdictions if the legal frameworks are inconsistent across jurisdictions. Furthermore, because AI technology itself is highly complex and rapidly developing, it is not possible to predict all of the legal, operational or technological risks that may arise relating to the use of AI.

Risks Related to Our Intellectual Property

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

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

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

The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the U.S. or in other countries. Our pending PCT patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. For example, any issued patents might not cover the pharmaceutical composition of the product candidate that is ultimately commercialized following regulatory approval. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may ultimately obtain. Even if patents do successfully issue and even if such patents cover our product candidates, 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 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 product candidates following regulatory approval. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates following regulatory approval, 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 product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our product candidates following regulatory approval. Any such outcome could have a materially adverse effect on our business. Our pending patent applications cannot be enforced against third parties practicing the claims in such applications unless and until a patent issues from such applications.

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

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

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

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

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

The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or, following approval, commercialize product candidates without infringing third-party patent rights or result in our breach of agreements pursuant to which we license such rights to our collaborators or licensees. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize product candidates. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The length of our patent terms may be inadequate to protect the competitive position of our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, are limited. Even if patents covering product candidates are obtained, once the patent life has expired, we may be open to competition from other products or product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product 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 product candidates.

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

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

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

Our ability to develop and 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, following approval, commercialization of our product candidates may require us to enter into additional license or collaboration agreements.

Our current license agreements impose, and future agreements may impose, various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we may not be able to market our product candidates following regulatory approval. 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 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, following approval, commercialize our product candidates. If our licenses are terminated, we may lose our rights to develop and market our technology and product candidates, lose patent protection for our product candidates and technology, experience significant delays in the development and, following approval, commercialization of our product candidates, or incur liability for damages. In addition, we may need to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our product candidates.

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

Furthermore, certain of our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. The intellectual property portfolio licensed to us by our licensors at least in some respects, may therefore be used by such licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. For example, Immunovant does not have rights to develop, manufacture, use or commercialize batoclimab or IMVT-1402 or file or enforce patents relating to these assets in territories other than the U.S., Canada, Mexico, the EU, the U.K., Switzerland, the Middle East, North Africa and Latin America, as such rights in other jurisdictions have been retained by HanAll Biopharma Co., Ltd. ("HanAll") or licensed by HanAll to third parties. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

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

Our commercial success depends in part on our avoidance of infringement, misappropriation and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, IPR and post-grant review before the USPTO, as well as oppositions and similar processes in other jurisdictions. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility, the risk increases that our products, product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our 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 product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidates following regulatory approval, 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, following approval, commercialize the applicable product candidate, unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could be time-consuming and divert the attention of senior management.

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

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because the competitors have substantially greater 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 product candidates following regulatory approval. 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, following regulatory approvals, market our product candidates.

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

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

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

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

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time-consuming, even if ultimately successful. In February 2022, Roivant's subsidiary, Genevant Sciences GmbH ("Genevant GmbH"), and Arbutus filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna and an affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19 (the "Moderna Action"). In November 2022, the District Court denied Moderna's partial motion to dismiss pursuant to 28 U.S.C. § 1498(a) ("§ 1498"). In March 2023, following the submission of a Statement of Interest in the case by the U.S. Government, the court reaffirmed its prior decision and again ruled that the complaint should not be partially dismissed on the basis of § 1498. On February 8, 2024, the court held a claim construction hearing on disputed terms within the claims of the asserted patents. On April 3, 2024, the court provided its claim construction ruling, in which it construed the disputed claim terms and agreed with Genevant GmbH and Arbutus' position on most of the disputed claim terms. Fact discovery and depositions are on-going and next steps include expert reports. In August 2024, the court approved an amended case schedule in the Moderna Action to accommodate certain outstanding discovery requests. A trial date has been set for September 2025. Separately, in April 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"). In July 2023, Pfizer and BioNTech filed an answer. The Pfizer Action is ongoing and the court has scheduled a claim construction hearing for December 2024.

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

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

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

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

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

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

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

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

The U.S. has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. For example, in June 2022, the World Trade Organization members agreed to waive certain patent rights with respect to COVID-19 vaccines. Any waiver of our patent or other intellectual property protection by the U.S. and other foreign governments, including with respect to Genevant's licensed lipid nanoparticle ("LNP") delivery technology as used in connection with messenger RNA vaccine delivery, could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We employ individuals who were previously employed at universities or other software, biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to not use the confidential information of their former employer, we may be subject to claims that we or our employees, consultants, independent contractors or other third parties have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our owned or licensed patents or patent applications. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, could limit the duration of the patent protection covering our technology and product candidates and could result in our inability to develop, manufacture or commercialize our product candidates following regulatory approval 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 product candidates following regulatory approval. 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 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 product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

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

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

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

If our performance does not meet market expectations, the price of our common shares may decline. In addition, the trading price of our common shares could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on the price of our common shares.

Factors affecting the trading price of our common shares may include:

- actual or anticipated fluctuations in our quarterly and annual financial results or the quarterly and annual financial results of companies perceived to be similar to it;
- changes in the market's expectations about operating results;
- our operating results failing to meet market expectations in a particular period;
- a Vant's operating results failing to meet market expectations in a particular period, which could impact the market prices of shares of a public Vant or the valuation of a private Vant, and in turn adversely impact the trading price of our common shares;
- receipt of marketing approval for a product 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 now that we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq. We also expect that compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and increased disclosure requirements will substantially increase our legal and financial compliance costs. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain blended director and officer liability insurance and forced us to forego securities and corporate protection coverage. We cannot predict or estimate the amount or timing of additional costs we have incurred and will continue to incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. As a result, you may not receive any return on an investment in our common shares unless you sell your shares 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 U.K. We currently have subsidiaries in the U.S., U.K., Switzerland and certain other jurisdictions. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable taxing authorities. If taxing authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions between two or more affiliated companies, they could require such affiliated companies to adjust their transfer prices and thereby reallocate the income between such affiliated companies to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If taxing authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase its consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

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

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

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

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock-based compensation; (6) changes in tax laws (including tax treaties) or the interpretation of such tax laws (including tax treaties) and changes in U.S. generally accepted accounting principles; (7) challenges to the transfer pricing policies related to our structure; (8) potential taxation under the OECD BEPS 2.0; and (9) potential limitation on tax attributes due to ownership changes (i.e. Internal Revenue Code 382 and 383) or expiration.

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

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

We believe that we were not classified as a CFC for the taxable year ended March 31, 2024. However, our non-U.S. subsidiaries will be classified as CFCs for the taxable year ended March 31, 2024. For U.S. holders who hold 10% or more of the combined voting power or value of our common shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the IRS. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the combined voting power or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing of our common shares.

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

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

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset. If we are a CFC (determined by disregarding certain downward attribution rules) and not publicly traded for the relevant taxable year, however, the test shall be applied based on the adjusted basis of our assets. Because our common shares should be considered to be "publicly traded" for the taxable year that ended on March 31, 2024, we would apply the 50% passive asset test using the fair market value of our assets. In addition, our status may also depend, in part, on how quickly we utilize our cash on-hand and cash from future financings in our business.

Based on the foregoing, with respect to the taxable year that ended on March 31, 2024, we believe that we were not a PFIC based in part upon the fair market value of our assets, including any goodwill and intangible property, and the nature and composition of our income and assets.

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

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

Issuer Purchases of Equity Securities

During the three and six months ended September 30, 2024, we repurchased 9,984,350 and 81,235,433 common shares, respectively, for $116.9 million and $765.3 million, respectively, including 960,692 common shares which were repurchased on September 30, 2024 with a settlement date of October 1, 2024. As of September 30, 2024, we were authorized to repurchase up to $734.7 million of our common shares.

The following table summarizes our common share repurchase transactions for the three months ended September 30, 2024:

Period	Total Number of Common Shares Purchased[(1)]	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Program[(2)]	Approximate Dollar Value of Common Shares that May Yet Be Purchased Under the Program[(2)]
				(in millions)
July 1 – 31, 2024	—	—	—	$ 851.6
August 1 – 31, 2024	1,150,573	$ 11.29	1,150,573	$ 838.6
September 1 – 30, 2024	8,833,777	$ 11.76	8,833,777	$ 734.7
Total	9,984,350		9,984,350	

(1) The total number of common shares purchased set forth in this column is based on the trade date of the repurchase transaction (not the settlement date of the repurchase transaction), including 960,692 common shares which were repurchased on September 30, 2024 with a settlement date of October 1, 2024.

(2) On April 2, 2024, we announced that our board of directors had authorized a common share repurchase program, allowing for repurchases of Roivant common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses). The timing and total amount of common shares repurchased depends on several factors, including the market price of our common shares, general business, macroeconomic and market conditions and other investment opportunities. Under the repurchase program, purchases may be conducted through open market transactions, tender offers or privately negotiated transactions, including the use of trading plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended. See Note 8–Shareholders' Equity in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information related to share repurchases. Table excludes fees and commissions payable in connection with common share repurchases.

* In addition to the repurchase transactions set forth above, during the six months ended September 30, 2024, we withheld 2,384,468 common shares associated with net share settlements to cover (i) tax withholding obligations upon the vesting and settlement of equity incentive awards issued under our equity incentive plans, including RSUs and CVARs, and (ii) the payment of the exercise price of certain stock options.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1*#	Agreement and Plan of Merger, dated September 17, 2024, by and among Dermavant Sciences Ltd., Organon & Co., Organon Bermuda Ltd. and Roivant Sciences Ltd.	8-K	001-40782	2.1	September 23, 2024
10.45*#	License Agreement by and between Bayer Aktiengesellschaft and Pulmovant, Inc., dated as of July 27, 2023.	—	—	—	Filed herewith
10.46*#	First Amendment to the License Agreement by and between Bayer Aktiengesellschaft and Pulmovant, Inc., dated as of September 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.

Dated: November 12, 2024

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

Exhibit 10.45

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

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement"), effective as of the date of the last signature (the "Effective Date"), is entered into by and between Bayer Aktiengesellschaft having a place of business at [***] ("Bayer") and Pulmovant, Inc., having a place of business at [***] ("Licensee"). Bayer and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

BACKGROUND

WHEREAS:

A. Bayer owns or Controls from its Affiliate Bayer Pharma AG certain patent rights, know-how and other intellectual property relating to the Licensed Compound and the Licensed Products (as hereinafter defined);

B. Licensee is a wholly-owned subsidiary of Roivant Sciences Ltd. which is experienced in the discovery, development, and commercialization of pharmaceutical products.

C. Licensee desires to obtain from Bayer, and Bayer desires to grant to Licensee, an exclusive license to Exploit the Licensed Compound and the Licensed Products in the Field in the Territory, on the terms and subject to the conditions set forth in this Agreement, and the Parties will cooperate as described herein with the shared objective that the Licensed Compounds and the Licensed Products are Exploited by Licensee as set forth in this Agreement.

NOW, THEREFORE, in consideration of the recitals above and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS

1.1 "Accounting Standards" means [***].

1.2 "Affiliate" means any business entity controlled by, controlling, or under common control with a Party hereto. For the purpose of this definition, a business entity shall be deemed to "control" another business entity, if it (i) owns directly or indirectly, more than fifty percent (50%) of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity having the power to vote on or direct the affairs of such business entity, as applicable (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), or (ii) possesses, directly or indirectly, the power to direct or cause the direction of the policies and management of such business entity, as applicable, whether by the ownership of stock, by contract or otherwise.

1.3 "Annual" or "Annually" means a period of twelve (12) consecutive months ending on March 31 or any partial period thereof immediately following the Effective Date or immediately prior to the termination or expiration of this Agreement.

1.4 "Business Day" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by law to be closed in (i) Berlin, Germany, or (ii) Leverkusen, Germany, or (iii) New York, New York.

1.5 "Change of Control" means , with respect to a Party, [***].

1.6 "Combination Licensed Product" means a Licensed Product for use in the Field sold in a single stock keeping unit (SKU) for a single selling price, containing or incorporating a Licensed Compound in combination with one or more other therapeutic active pharmaceutical ingredients, but, in any event, excluding devices, drug delivery vehicles, adjuvants, solubilizers and excipients. A Combination Licensed Product is deemed included within Licensed Product when that defined term is used herein.

1.7 "Commercially Reasonable Efforts" means, with respect to an obligation under this Agreement applicable to a Licensed Product, such level of efforts, budget and resources as [***]. Notwithstanding the foregoing, Licensee's Commercially Reasonable Efforts shall be determined on a country-by-country and Indication-by-Indication basis for each Licensed Compound or Licensed Product, as applicable, and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular country or Indication shall change over time, reflecting changes in the status of such Licensed Compound or Licensed Product, as applicable, and the country or Indication involved.

1.8 "Commercialization" and "Commercialize" means all activities undertaken before or after Marketing Authorization relating to use for commercial purposes, promotion, marketing, medical support, distribution (including transporting, customs clearance, warehousing, invoicing, handling, and delivering products to customers), sale, offer for sale, sampling, export for use, sale and distribution, and import for use, sale and distribution of a pharmaceutical product, including sales force efforts, detailing, advertising, market research, market access (including price setting and reimbursement activities), medical education and information services, publication, scientific and medical affairs, advisory and collaborative activities with opinion leaders and professional societies (including symposia), sales force training, sales (including receiving, accepting, and filling product orders), and all regulatory affairs related to any of the foregoing. For clarity, Commercialization shall include any commercial activities conducted in preparation for the launch of a Licensed Product but shall not include Development and Manufacturing.

1.9 "Competing Product" means any [***].

1.10 "Confidentiality Agreement" means that certain Confidentiality Agreement between Bayer Healthcare Pharmaceuticals, Inc. and Roivant Sciences, Inc., dated [***].

1.11 "Control" or "Controlled" means, with respect to Know-How, Patent Rights or Confidential Information, the possession of the legal authority or right to grant a license or sublicense under such Know-How or Patent Rights or to disclose or grant access to or a right to use or reference such Confidential Information on the terms and conditions set forth in this Agreement without violating the rights of or the terms of any agreement with any Third Party at the time a Party would first be required as agreed hereunder to grant such license, sublicense, access or right to use or reference or make such disclosure.

1.12 [***]

1.13 [***]

1.14 "Cover" or "Covering" means, with respect to a Patent Right, a Licensed Compound or Licensed Product or its Exploitation that, but for a license or sublicense under a particular Valid Claim of such Patent Right granted under this Agreement, the making, using, offering for sale, selling or importing of such Licensed Compound or Licensed Product would infringe such Valid Claim or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue without change and become a Valid Claim.

1.15 "Development" and "Develop" means to engage in research and development activities (including nonclinical studies, preclinical studies, clinical trials, CMC development and all regulatory activities necessary to securing and maintaining the Marketing Authorization for a Licensed Product).

1.16 "EMA" means the European Medicines Agency, or any successor agency thereto.

1.17 "Executive Sponsors" shall mean (a) with respect to Bayer, [***] and (b) with respect to Licensee, [***] in each case (a) and (b), or such other person designated by one Party to the other Party in writing from time to time.

1.18 "Exploit" or "Exploitation" means to use, Develop, have Developed, Commercialize, have Commercialized, Manufacture and have Manufactured.

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

1.20 "FDA" means the United States Food and Drug Administration of the Department of Health and Human Services, or any successor agency thereto.

1.21 "Field" means the prevention, treatment, mitigation, cure and/or diagnosis of any disease in humans and/or in animals.

1.22 "First Commercial Sale" means the first invoiced sale of a Licensed Product by a Licensee Party in any country after grant of a Marketing Authorization, provided that where such a first commercial sale has occurred in a country for which Pricing Approval is necessary, then such sale shall not be deemed a First Commercial Sale until such Pricing Approval has been obtained in such country. For the avoidance of doubt, supply of a Licensed Product as samples or to patients for treatment IND sales, compassionate use, named patient use, clinical trials or other similar purposes shall not be considered a First Commercial Sale.

1.23 "GCP" means regulations and published guidelines related to current good clinical practices that relate to the conduct of clinical studies in humans including the regulations set forth in 21 CFR 50, 54, 56, 312 and 314 promulgated by the FDA, the ICH Harmonized Tripartite Guideline for Good Clinical Practice and similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.

1.24 "Generic Product" means, with respect to a Licensed Product being sold in any country, a product that (a) contains the same active pharmaceutical ingredient as such Licensed Product, (b) has received Marketing Authorization from the Regulatory Authority in such country by reference to a Licensee Party's Marketing Authorization for such Licensed Product in such country based on a demonstration of bio-equivalence to such Licensed Product, and (c) is sold in such country by a Third Party that is not a Sublicensee and did not purchase such product in a chain of distribution that included Licensee or any of its Affiliates or Sublicensees.

1.25 "GLP" means regulations and published guidelines related to current good laboratory practices that relate to the processes and conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing of chemicals for the protection of man, animals and environment, including the regulations set forth in 21 CFR 58 promulgated by the FDA and similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.

1.26 "GMP" means regulations and published guidelines related to current good manufacturing practices that relate to the testing, manufacturing, processing, packaging, holding or distribution of drug or biologic drug substances and finished drugs or biologics including the regulations set forth in 21 CFR 210 and 211 promulgated by the FDA and similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.

1.27 "IND" means a filing with a Regulatory Authority that must be made prior to commencing clinical testing in humans including, in the United States, an Investigational New Drug application (as defined in the FD&C Act and the regulations promulgated thereunder (21 CFR 312.1 et seq)), in the European Union, a Clinical Trial Application (CTA), or in any other jurisdiction, a comparable filing and, in each case, any amendments and supplements thereto.

1.28 "Indication" means any separately defined and distinct class of a human disease, syndrome, aesthetic or medical condition which a Licensed Product is intended to treat or prevent, which use is the subject of a separate clinical trial filing and/or a separate Marketing Authorization process resulting in the addition of such Indication in the product label for such Licensed Product, but excluding different lines of treatment or patient populations (e.g., pediatric) for the same disease, syndrome, aesthetic or medical condition. For clarity and by way of example, [***]; provided, however, that, subpopulations or patients with a primary disease or condition, however stratified (including stratification by stages of progression, particular combinations of symptoms associated with the primary disease or condition, prior treatment courses, response to prior treatment, family history, clinical history, genotype, phenotype, or other stratification) shall not be deemed to be separate "Indications".

1.29 "Know-How" means all commercial, technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, and whether or not patentable, including inventions (whether patentable or not), invention disclosures, discoveries, trade secrets, know-how, technology, methods, plans, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, concepts, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), and manufacturing documentation, in all cases whether in written, electronic or any other tangible or non-tangible form, including information related to materials, samples, assays, compounds, compositions, formulas or formulations. [***].

1.30 "Laws" means all applicable laws (including anti-corruption laws), statutes, rules, regulations (including cGCP, cGLP and cGMP), orders, judgments and/or ordinances of any Regulatory Authority, governmental authority or court or any subpoena of a competent court having effect from time to time in the Territory, as well as any security exchange rules.

1.31 "Licensed Compounds" means [***].

1.32 "Licensed Know-How" means any Know-How owned or Controlled by Bayer or any of its Affiliates [***].

1.33 "Licensed Patent Rights" means the Patent Rights [***].

1.34 "Licensed Patent Rights A" means any and all of the Licensed Patent Rights [***].

1.35 "Licensed Patent Rights B" means any and all of the Licensed Patent Rights [***].

1.36 "Licensed Product" means any product that contains or comprises a Licensed Compound.

1.37 "Licensed Technology" means, collectively, the Licensed Patent Rights and Licensed Know-How.

1.38 "Licensee Party" means Licensee, its Sublicensees and any of Licensee's or its Sublicensee's Affiliates.

1.39 "Major Market" means [***].

1.40 "Manufacture" and "Manufacturing" means all activities related to the making (and having made), manufacture, synthesis, production, processing, purifying, formulating, filling, finishing, packaging, labeling, inspection, receiving, holding, storage, and shipping of a product.

1.41 "Marketing Authorization" means any approval, license, registration, permit or authorization required from the relevant Regulatory Authority of a country or jurisdiction to market, import and sell the Licensed Product in such country or jurisdiction: for the avoidance of doubt, Marketing Authorization does not include any Pricing Approval.

1.42 "NDA" means, with respect to a Licensed Product, a filing serving to apply for Marketing Authorization including, in the United States, a New Drug Application (as defined in the FD&C Act and the regulations promulgated thereunder (21 CFR 314)), in the European Union, a Marketing Authorization Application (MAA), or, in any other jurisdiction, a comparable filing, and, in each case, any amendments and supplements thereto.

1.43 "Net Sales" means [***]

[***]

[***]

[***]

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[***]

[***]

[***]

[***]

[***]

[***]

1.44 "Patent Rights" mean:

(a) all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings, patent applications, utility models, design patents and design rights filed in any country of the world including provisional patent applications;

(b) all patents, patent applications, utility models, design patents and design rights filed either from such patents, patent applications, utility models, design patents, design rights or provisional patent applications or claiming priority from any of these, including any continuation, continuation-in part, division, provisional, converted provisional and continued prosecution applications, or any substitute application;

(c) any patent issued with respect to or in the future issued from any such patent applications;

(d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including reissues, re-examinations, renewals, extensions (including any supplementary protection certificates and the like), substitutions, confirmations, registrations, revalidations, revisions and additions of the foregoing patents, patent applications, utility models, design patents and design rights; and

(e) any foreign counterparts of the foregoing.

1.45 "Person" means an individual or firm, corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, or other entity of any kind.

1.46 [***]

1.47 [***]

1.48 "Phase 1 Clinical Trial" means a human clinical trial of a Licensed Compound or Licensed Product, the principal purpose of which is to determine initial tolerance or safety of such Licensed Product in healthy individuals and patients, including, in the United States, a human clinical trial as described in 21 CFR 312.21(a), as amended from time to time, or, in a country other than the United States, a similar clinical study prescribed by the applicable Regulatory Authority.

1.49 "Phase 2 Clinical Trial" means a small scale human clinical trial of a Licensed Compound or Licensed Product on patients, in any country, including possible pharmacokinetic studies, the principle purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain information about such product's efficacy to permit the design of further clinical trials or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable law or otherwise, including the trials referred to in US Code Title 21 CFR. §312.21(b), as amended from time to time, or, in a country other than the United States, a similar clinical study prescribed by the applicable Regulatory Authority.

1.50 "Phase 3 Clinical Trial" means a pivotal human clinical trial of a Licensed Compound or Licensed Product on patients, in any country, which trial is designed to:

(a) establish the risk benefit profile of the product;

(b) define warnings, precaution and adverse reactions that are associated with the product; and

(c) support Marketing Authorization of such product; or a similar clinical study prescribed by the regulatory authorities, from time to time, pursuant to applicable law or otherwise, including the trials referred to in US Code Title 21 CFR. §312.21(c), as amended from time to time, or, in a country other than the United States, a similar clinical study prescribed by the applicable Regulatory Authority.

1.51 "Pricing Approval" means, with respect to a particular country or jurisdiction, all applicable governmental pricing and reimbursement approvals required from the relevant Regulatory Authority under applicable Laws of such country or jurisdiction to Commercialize a Licensed Product in such country or jurisdiction.

1.52 "Publication" means an article in a peer-reviewed journal or a presentation, poster, or abstract for a scientific conference.

1.53 "Quarter" or "Quarterly" means a period of three (3) consecutive months corresponding to the calendar quarters commencing on the first day of January, April, July or October, or any partial period thereof immediately following the Effective Date or immediately prior to the termination or expiration of this Agreement.

1.54 "Regulatory Authority" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.55 "Regulatory Exclusivity" shall mean, with respect to a Licensed Compound or Licensed Product in any country or other jurisdiction in the Territory, any exclusive right to market and sell, other than Patent Rights, conferred by a Regulatory Authority in such country or other jurisdiction after grant of Marketing Authorization of such Licensed Product in such country that prohibits a Third Party from Commercializing a Generic Product, including data exclusivity, marketing exclusivity, orphan exclusivity, pediatric exclusivity, and exclusivity as a new chemical entity (NCE) as defined by the Laws of such country or jurisdiction.

1.56 "Reversion Product(s)" means [***].

1.57 "Reversion Technology" means, [***].

1.58 "Sublicensee" shall mean a Third Party (except an Affiliate) to whom Licensee has granted a sublicense in accordance with Section 2.2, for clarity, beyond the mere right to purchase Licensed Products from Licensee and its Affiliates.

1.59 "Taxes" means any U.S. and non-U.S. federal, state, local, regional, municipal, or other tax or taxation, levy, duty, charge, withholding or other assessment of any kind (including any related fine, penalty, addition to tax, surcharge, or interest) imposed by, or payable to, a governmental authority, including sales, use, excise, stamp, transfer, property, value added, goods and services, withholding, and franchise taxes (whether imposed directly or through withholding, and whether or not disputed).

1.60 "Territory" shall mean all countries of the world.

1.61 "Third Party" means any entity other than a Licensee, Bayer or Licensee's or Bayer's Affiliates.

1.62 "Third Party Action" means, with respect to a Patent Right, a declaratory judgment action, *inter partes* review, opposition proceeding, appeal proceeding, interference, or other action or court proceeding challenging any such Patent Right through a legal or administrative proceeding.

1.63 "Third Party IP" means any Patent Rights that is (a) necessary to Exploit any Licensed Compound or Licensed Product in the Field in the Territory or (b) reasonably useful from a time or cost perspective for the Exploitation of any Licensed Compound or Licensed Product in the Field in the Territory, in each case (a) and (b) that is owned or controlled by a Third Party and not owned or Controlled by either Party or any of its Affiliates.

1.64 "US" means the United States of America and its territories and commonwealths, including, without limitation, the Commonwealth of Puerto Rico.

1.65 "Valid Claim" means (a) a claim of an issued and unexpired Licensed Patent Right (including any patent claim the term of which is extended by any extension, supplementary protection certificate, patent term restoration, or the like), which has not lapsed, been abandoned, been held revoked, or been deemed unenforceable or invalid by a non-appealable decision or an appealable decision from which no appeal was taken within the time allowed for such appeal of a court or other governmental agency of competent jurisdiction, or (b) [***].

Additional Definitions: The following table identifies the location of definitions set forth in various Sections of this Agreement:

Defined Term	Section Reference
Acquired Competing Program	Section 3.3.2(b)
Alliance Manager	Section 3.1
API	Section 7.1.2
ARDS-Field	Section 3.3.1
[***]	Section 6.4.3.2
Auditor	Section 5.9.1(i)
[***]	Section 1.31
Bayer Exclusivity Period	Section 3.3.2(a)
Bayer Indemnitee	Section 10.2
Breach Notice	Section 11.3
Commercialization Wind-Down Period	Section 11.6.4(e)(i)

Competing Program	Section 3.3.2(a)
Confidential Information	Section 6.1.1
Country List	Section 9.2.2
Cure Plan	Section 11.3
Disclosing Party	Section 6.1.1
Disputed Matter	Section 12.1
Document Transfer Deficiency Notice	Section 2.3(ii)
Documentation Review Date	Section 2.3(ii)
DSUR	Section 2.3(iii)(a)
Employee Data	Section 13.3
GDPR	Section 13.1
Human Data	Section 13.4
IND Transfer Date	Section 3.4.1
Indemnified Party	Section 10.3.1
Indemnifying Party	Section 10.3.1
Losses	Section 10.1
Licensee Indemnitee	Section 10.1
New Agreement	Section 11.6.4(f)
Patent Challenge	Section 11.5
Payee	Section 5.5.1
Paying Party	Section 5.5.1
Pharmacovigilance Agreement	Section 2.3(iii)
Qualified Assignment	Section 14.4.1(c)
Receiving Party	Section 6.1.1
Regulatory Transfer Period	Section 3.4.2

Royalty Payment	Section 4.3.1
Royalty Rate	Section 4.3.1
Royalty Term	Section 4.3.2
Rules	Section 12.2
Semi-Annually	Section 3.5.1
Solvent	Section 14.4.1(c)(iii)
Term	Section 11.1
Third Party Claim	Section 10.1
Transfer Tax	Section 5.7
VAT	Section 5.4
VDR	Section 8.3
Withholding Tax	Section 5.5.1
Yearly	Section 3.5.1

2. LICENSES, TECHNOLOGY TRANSFER

2.1 License to Licensee. Subject to the terms and conditions of this Agreement, including, for clarity, Section 3.3.1, Bayer hereby grants to Licensee an exclusive (even as to Bayer and its Affiliates) license (with the right to grant sublicenses pursuant to Section 2.2 below) under the Licensed Technology to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory. For the avoidance of doubt, but subject to Section 3.3.2, nothing in this Section 2.1 shall limit Bayer's and its Affiliates' right to use or have used the Licensed Technology to Exploit any other compounds other than the Licensed Compounds and any other products other than the Licensed Products.

2.2 Sublicenses. Subject to the terms and conditions of this Agreement, including, for clarity, Section 3.3.1, Licensee shall have the right to grant sublicenses, through multiple tiers of Sublicensees, under the licenses and rights granted in Section 2.1 above, to its Affiliates and Third Parties. Each sublicense agreement shall be consistent with all the terms and conditions of this Agreement applicable to the Sublicensee under such sublicense agreement, including provisions at least as protective of Bayer as the provisions of this Agreement on confidentiality, indemnification, audits and (in case of an exclusive sublicense) diligence. Licensee shall be responsible for ensuring that the performance by any of its Sublicensees hereunder is in accordance with the applicable terms of this Agreement, and the grant of any such sublicense shall not relieve Licensee of its obligations under this Agreement. Within [***] after the effective date of a sublicense agreement that Licensee enters into with an Affiliate or a Third Party granting Development and Commercialization rights with respect to the Licensed Products, Licensee shall provide Bayer with written notice of such sublicense, which notice shall include [***]. For the avoidance of doubt, any act or omission by a Sublicensee that, if committed by Licensee, would be a breach of this Agreement, shall constitute a breach of this Agreement by Licensee.

2.3 Technology Transfer; Pharmacovigilance Agreement. Subject to Section 7.2, which exhaustively covers the transfer of technology related to the Manufacture of the API and the Licensed Products, Bayer shall, or shall cause its Affiliates to complete the following.

(i) Within the applicable period after the Effective Date specified in Exhibit 2.3, [***], transfer the Licensed Know-How and related materials to Licensee specified in Exhibit 2.3. For a period of [***] after the Effective Date, [***] Bayer shall provide Licensee with such Know-How (which, for clarity, constitutes Licensed Know-How) in a manner consistent with that specified in Exhibit 2.3 for similar Licensed Know-How. Notwithstanding the foregoing, at any time following such [***] period and upon Licensee's request, Bayer shall use reasonable efforts, [***], to provide additional documents or material that embody Licensed Know-How specifically related to the Development or Commercialization of the Licensed Compounds and Licensed Products in the Field in Bayer or any of its Affiliates' possession and owned or Controlled by it to Licensee [***]. [***].

(ii) Licensee will have [***] following receipt of all documents specified in [***] to review whether such documents are complete for such purpose, and if not, provide written notice (a "Document Transfer Deficiency Notice") to Bayer thereof, including the document title and a brief description of items missing or incomplete. Following the receipt of such notice from Licensee, Bayer shall use reasonable efforts to [***] provide the applicable documents to Licensee (in any event within [***]). If Licensee does not provide a Document Transfer Deficiency Notice to Bayer, the documents will be deemed acceptable upon the conclusion of such [***] period (such date or the date on which Bayer provides to Licensee all documents set forth in a Document Transfer Deficiency Notice, the "Documentation Review Date"). [***].

(iii) Within [***] after the Effective Date, the Parties will negotiate in good faith and execute a pharmacovigilance agreement (the "Pharmacovigilance Agreement") covering:

[***]

[***]

(iv) Bayer will use reasonable efforts to respond [***], and in any event within [***], to Licensee's reasonable requests during Bayer's normal business hours for Bayer to provide to Licensee, for a period of [***] following the Effective Date [***], technology transfer and enablement assistance (via virtual meetings with pre-aligned agendas and answering questions by email) related to the Licensed Know-How (excluding Manufacturing Know-How which is exhaustively covered by Section 7.2) as is reasonably necessary to carry out the activities specified in this Section 2.3 (i) and (ii); [***].

2.4 [***]

2.5 [***]

2.6 [***]

2.7 No Further Rights. Only the licenses granted pursuant to the express terms of this Agreement shall be of any legal force or effect. No other license rights shall be granted or created by implication, estoppel or otherwise.

3. ALLIANCE MANAGERS / DEVELOPMENT / DILIGENCE

3.1 Alliance Managers. As soon as practicable after the Effective Date, but no later than [***] after the Effective Date, each Party shall nominate a representative to act as its alliance manager for the cooperation under this Agreement (the "Alliance Manager"). The Alliance Managers shall serve as the key contact point between the Parties and, without limiting the dispute resolution process according to Section 12.1, attempt to resolve any conflicts. A Party may replace its Alliance Manager at any time by providing written notice to the other Party.

3.2 Diligence; Control.

3.2.1 Licensee shall use Commercially Reasonable Efforts to Develop, obtain and maintain Marketing Authorization, and, following receipt of Marketing Authorization, Commercialize [***]. Licensee shall have the sole responsibility, at its sole cost, for the Development, Commercialization and, subject to Section 7.2, Manufacture of the Licensed Compounds and Licensed Products. All INDs and all NDAs will be submitted in the name of a Licensee Party, and all Marketing Authorizations will be held and owned by a Licensee Party. Failure by Licensee to use Commercially Reasonable Efforts as described in this Section 3.2.1 will constitute a breach of material obligation and, for clarity Section 11.3 applies.

3.2.2 As soon as Licensee anticipates to suspend the Development of Licensed Products for a period of at least [***], Licensee will notify Bayer in writing [***]. Bayer shall then have the right to request a meeting (either via telephone, video or in-person) which shall take place no later than [***] after such meeting has been requested, and Licensee shall make available for such meeting such employees and representatives with appropriate expertise and knowledge regarding the Development activities. Such meeting shall be set-up by the Alliance Managers of the Parties [***].

3.3 Exclusivity.

[***]

[***]

3.4 IND Assignment; Regulatory Responsibility.

3.4.1 No later than [***] following the Documentation Review Date, [***], Bayer shall initiate to assign, on behalf of itself and its Affiliates, and shall cause its Affiliates to assign, to Licensee all of its and its Affiliates' rights, title and interest in and to the IND having the number [***]. The Parties shall cooperate in executing such assignment, with the effective date of assignment to occur on a date mutually agreed by the Parties (the "IND Transfer Date").

3.4.2 For the period beginning on the Effective Date and ending on the IND Transfer Date (the "Regulatory Transfer Period"), Bayer shall continue to maintain regulatory filings for the Licensed Compound at Licensee's direction. [***]; provided that Bayer shall not be required to take any action on behalf of Licensee that is not in compliance with applicable Laws, or otherwise not in compliance with Bayer's internal policies and standards.

3.4.3 In the event of failure to obtain the assignment contemplated under Section 3.4.1, Bayer, on behalf of itself and its Affiliates, hereby grants to Licensee, its Affiliates and its Sublicensees (without any further action required on the part of Bayer and its Affiliates, whose authorization to file this consent with any Regulatory Authority of the Territory is hereby granted effective as of the Effective Date), an authorization to copy, access, reference, and otherwise use (at no cost to Licensee), the IND application and filing referenced in Section 3.4.1 made by or on behalf of Bayer or any of its Affiliates with or to the FDA [***]. Bayer shall provide to Licensee a signed statement to the effect of the foregoing and, solely if required by the FDA, shall take such actions as may be reasonably requested by Licensee to give effect to the intent of this Section 3.4.3.

3.4.4 Subject to Section 3.4.2, Section 2.3(ii) and the terms of the Pharmacovigilance Agreement, as between the Parties, Licensee shall be responsible, and act as the sole point of contact, for communications with Regulatory Authorities in connection with the Development, Commercialization, and Manufacturing of the Licensed Compounds and the Licensed Products in the Field in the Territory. [***].

3.5 Reports; Discussion of the Reports.

3.5.1 Reports. Licensee shall keep Bayer informed by providing to the Alliance Manager of Bayer [***].

3.5.2 Discussion of the Reports. If requested in writing by the Alliance Manager of Bayer upon the receipt of any report delivered by Licensee pursuant to Section 3.5.1, and upon reasonable advance notice, Licensee shall make available to Bayer representatives of Licensee with the appropriate expertise and knowledge of the activities undertaken to perform the Development and/or Commercialization to answer reasonable questions posed by Bayer [***] (either via telephone, video or in-person) per such report, such meeting to be held upon request by Bayer and be set-up by the Alliance Managers of the Parties; for clarity, the aforementioned representatives of Licensee shall participate in such meeting. [***].

3.6 Records. During the Term (or such longer period of time as may be required by Laws), Licensee shall prepare and maintain complete and accurate records regarding the Development and Commercialization activities conducted by it hereunder with respect the Licensed Compounds and Licensed Products by or on behalf of Licensee Parties. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development and Commercialization activities. [***].

3.7 Compliance with Laws. In respect of any Development or Commercialization activities to be performed by Licensee, Licensee agrees to perform its obligations in compliance with Laws.

4. CONSIDERATION

4.1 Upfront Payment. Subject to the terms and conditions of this Agreement, in partial consideration of the rights granted to it by Bayer under this Agreement, Licensee shall pay to Bayer an upfront payment of thirteen million US Dollars (US$13,000,000) [***]. Such upfront payment will be unconditional and non-refundable, and as such shall not be subject to any offset, credit, reduction or repayment for any reason whatsoever, whether provided for in this Agreement or not.

4.2 Milestone Payments.

4.2.1 Subject to the remainder of this Section 4.2, in partial consideration of the rights granted to it by Bayer under this Agreement, upon the first (1st) achievement of the corresponding development or regulatory milestone event by a Licensed Product or sales milestones event for all Licensed Products by all Licensee Parties, Licensee shall make the following one-time payments to Bayer:

	Milestone	Amount
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
6	[***]	[***]
7	[***]	[***]
8	[***]	[***]
9	[***]	[***]
10	[***]	[***]

4.2.2 Licensee shall provide written notice to Bayer (a) of any occurrence of any of the development or regulatory milestone events set forth above (1-6) no later than [***] after the occurrence of the relevant milestone event has been achieved and (b) of any occurrence of any of the sales milestone events set forth above (7-10) no later than [***] after the end of the applicable [***] in which the relevant milestone event has been achieved, in each case (a) and (b) in accordance with Section 4.2.1. Following such notice, Bayer shall (i) in the case of a development or regulatory milestone event, [***] and (ii) in the case of a sales milestone even, [***], issue an invoice for the corresponding milestone payment, and Licensee shall pay to Bayer the invoiced milestone payment, in accordance with Section 5.1.

4.2.3 All of the foregoing milestone payments will be paid to Bayer by Licensee only one-time irrespective of how many Licensed Products achieve a milestone event and no milestone payments will be payable to Bayer under this Agreement for Indications subsequent to the second Indication.

4.3 Royalty Payments.

4.3.1 Royalty Rate. Subject to the remainder of this Section 4.3, in partial consideration of the rights granted to it by Bayer under this Agreement, on a Licensed Product-by-Licensed Product basis, Licensee shall pay to Bayer royalty payments on the Annual Net Sales of such Licensed Product sold in the Territory by or on behalf of the Licensee Parties during the Royalty Term for such Licensed Product ("Royalty Payments") at the applicable royalty rate set forth below (each, a "Royalty Rate").

Portion of Annual Net Sales of a Licensed Product	**Royalty Rate**
[***]	[***]
[***]	[***]

4.3.2 Royalty Term. Royalties Payments shall be paid on Net Sales on a Licensed Product-by-Licensed Product and country-by-country basis from the First Commercial Sale of such Licensed Product in such country in the Territory by or on behalf of Licensee or its Affiliates or Sublicensees until the later of (a) the expiration of the last to expire Valid Claim of a Licensed Patent Right in such country, (b) the expiration of Regulatory Exclusivity for such Licensed Product in such country, and (c) [***] after the date of the First Commercial Sale of such Licensed Product in such country (the "Royalty Term"). For the avoidance of doubt, (i) the Net Sales value shall be reset on an Annual basis, and (ii) from and after the expiration of the Royalty Term for a Licensed Product in a country, Net Sales of such Licensed Product in such country shall be excluded for purposes of calculating the Net Sales thresholds set forth in the table of Section 4.2.1.

4.3.3 Royalty Reductions.

(a) Generic Entry. Subject to Section 4.3.3(d), if, on a country-by-country and Licensed Product-by-Licensed Product basis, a Third Party that is not a Licensee Party receives Marketing Authorization for and commences commercial sale of a Generic Product, the applicable Royalty Rates for such Licensed Product in such country shall be reduced by [***] beginning with the first [***] in which Net Sales of such Licensed Product in such country shall have for the first time decreased by [***] compared to the Net Sales of such Licensed Product in such country in the immediately preceding [***].

(b) Patent Expiry. Subject to Section 4.3.3(d), if the Royalty Term for a particular Licensed Product in a country extends beyond the time period set forth in Section 4.3.2(a), then the applicable Royalty Rates shall be reduced by [***] for such Licensed Product in such country during the portion of the Royalty Term that extends beyond the time period set forth in Section 4.3.2(a).

(c) Third Party Licenses. Subject to Section 4.3.3(d), if Licensee or its Affiliate or Sublicensee enters into an agreement with a Third Party in order to obtain a license or other right under any Third Party IP with respect to a Licensed Product in one or more countries in the Territory, Licensee or such Affiliate or Sublicensee shall be entitled to deduct from any Royalty Payments with respect to such Licensed Product in such country(ies) [***] of all amounts paid to such Third Party pursuant to the terms of such agreement, in each case to the extent reasonably allocable to such rights in such country.

(d) Royalty Floor. Notwithstanding anything to the contrary in the foregoing Sections 4.3.3(a) through (c), with respect to any Licensed Product in any [***], the operation of Sections 4.3.3(a) through (c) above, individually or in combination, shall not reduce by more than [***] the Royalty Payments that would otherwise have been due under Section 4.3.1 with respect to Net Sales of such Licensed Product in the applicable country(ies) during such [***]. Licensee shall have the right to carry forward on a country-by-country basis for a total of [***] any amounts that it was not able to credit on account of the royalty floor set forth in this Section 4.3.3(d) towards any Royalty Payments owed to Bayer in each such [***].

4.3.4 Royalty Reports. Starting from the date of First Commercial Sale of any Licensed Product in any country, Licensee shall submit within [***] after the end of each [***] a Microsoft Excel file showing: [***]. All amounts payable to Bayer pursuant to Section 4.3.1 will be paid within [***] after Licensee's receipt from Bayer of an invoice for such payment by wire transfer to the account specified in Section 5.1.

Even if there were no sales, Licensee shall provide a report indicating that no royalties are due.

5. PAYMENTS

5.1 Payment Date; Invoicing. Except as otherwise set forth in Section 4.1 and Section 4.3.4, all payments due hereunder by Licensee shall be made within [***] after Licensee's receipt from Bayer of an invoice for such payment by wire transfer to the following bank account or to such other bank account specified in writing in such invoice by Bayer to Licensee:

[***]

provided that all payments shall include a reference to this Agreement and its Parties.

Each invoice for payments shall be sent to Invoices@Roivant.com or to such other address as Licensee shall have last furnished in writing to Bayer at least [***] in advance.

5.2 Payments; Interest. Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. All payments not made by the due date set out in this Agreement shall be subject to late payment interest at [***] (or the maximum applicable legal rate of interest permitted by Law if lower). Interest shall be calculated based on the actual number of days in the interest period divided by 360 and shall be calculated from the due date (inclusive) until the date of payment (exclusive). If the prime rate is below zero, this rate will be deemed to be zero. The payment of such interest shall not limit Bayer from exercising any other rights it may have as a consequence of the lateness of any payment.

5.3 Currency. All payments under this Agreement will be made in US dollars. With respect to conversion of Net Sales in any currency other than US dollars to US dollars, the applicable Licensee Party shall convert the currency to US dollars using its then-current internal foreign currency translation method actually used on a consistent basis in preparing its financial statements, which shall be continuously audited and confirmed as being in compliance with accepted accounting standards (IFRS or US-GAAP, as applicable) by an independent certified public accountant.

5.4 VAT. All agreed consideration is exclusive of Value Added Tax ("VAT"). Subject to an assignment of this Agreement, as of the Effective Date, the Parties do not expect VAT to apply. If VAT is applicable, it shall be invoiced additionally, according to the applicable VAT law, by and paid to Bayer if Bayer is obliged to transfer such VAT to the respective tax authority. Bayer shall issue correct invoices in accordance with the applicable VAT-law.

5.5 Withholding Tax.

5.5.1 Any Party required to make a payment pursuant to this Agreement (hereinafter "Paying Party") to the other Party (hereinafter "Payee") shall be entitled to deduct and withhold from the amount payable the tax for which Paying Party is or may be held liable on behalf or for the account of Payee or in relation to taxes of Payee under any provisions of law ("Withholding Tax").

5.5.2 The Licensee herewith confirms that the licensed intellectual property is not allocated to a permanent establishment of the Licensee in Germany. The licensee will inform Payee in case the licensed intellectual property will be allocated to a permanent establishment of the licensee in Germany in the future.

5.5.3 If the tax rate for the Withholding Tax is actually reduced according to an applicable double taxation treaty or local law, no deduction shall be made or any deductions shall only be made at a reduced amount, as the case may be, only if Paying Party is timely furnished with the necessary documents by Payee (and, if required by the relevant jurisdiction, issued from the competent tax authority) which certify that the payment is exempt from tax or subject to a reduced tax rate.

5.5.4 The Paying Party shall use commercially reasonable efforts to notify Payee reasonably in advance of any payment with respect to which it takes the view that the requirements for a deduction and withholding are satisfied and it intends to make such deduction of Withholding Tax.

5.5.5 If a Withholding Tax deduction is required by Laws, Paying Party and Payee shall cooperate in good faith (i) to comply with all procedures in order to achieve an exemption / release from such deduction and withholding and (ii) to resolve any disagreement as to the Laws (if any). Any withheld Withholding Tax shall be treated as having been paid by Paying Party to Payee for all purposes of this Agreement. Paying Party shall timely forward the receipts certifying the payments of Withholding Tax to Payee. Any Withholding Taxes due to the assignment of this Agreement that would not have applied without such assignment shall be borne by the assigning Party unless the other Party has requested this assignment or approved the assignment (and the assigning Party has not otherwise agreed to compensate the non-assigning Party for such Withholding Taxes).

5.6 Taxes on Income. Each Party will be solely responsible for the payment of all Taxes imposed on its income arising directly or indirectly as a result of the transactions contemplated by this Agreement.

5.7 Transfer Tax. Each Party will be solely responsible for the payment of any transfer, stamp, sales, use, or similar taxes or obligations ("Transfer Tax") that will be assessed and legally owed by the respective Party against the respective tax authorities.

5.8 Records of Revenues and Expenses. Licensee shall retain, and shall procure that all Licensee Parties retain, true and accurate records and books of account containing all data necessary for the calculation of the amounts payable by Licensee to Bayer pursuant to the Agreement. Such books and records shall be kept for [***] following the [***] period to which they retain, or such longer period of time as may be required by Law.

5.9 Audit.

5.9.1 To validate Licensee's compliance with the Agreement in connection with its financial obligations under this Agreement, Bayer may, during the course of this Agreement and for [***] after termination of this Agreement, appoint an auditor, [***], to carry out an audit of Licensee's practices, procedures and records from time to time. Licensee shall cause any Sublicensee to allow Bayer to carry out an audit directly of such Sublicensee in accordance with this Section 5.9. Audits may be undertaken solely subject to the following conditions.

(i) Any such audits shall be undertaken by an independent certified public accountant, [***] (the "Auditor").

(ii) Any such audits shall be permitted to be conducted [***].

(iii) The Licensee Party will nominate a representative, familiar with all aspects of the Licensee Party's compliance with the Agreement in connection with the financial obligations of this Agreement to assist the auditor. The representative will provide prompt and reasonable access to all records and other information, as reasonably requested by the Auditor to assess Licensee's compliance with the Agreement in connection with its financial obligations under this Agreement.

(iv) The Auditor will enter a confidentiality agreement [***] governing the use and disclosure of such audited Licensee Party's information disclosed to the Auditor, [***].

(v) If an audit reveals that Licensee has underpaid royalties due, Bayer shall invoice Licensee for the underpaid amount; if the audit reveals that Licensee has overpaid royalties due, Bayer shall credit Licensee for the overpaid amount. For the avoidance of doubt, late payment interest shall be due on any underpaid amounts, calculated in accordance with Section 5.2.

(vi) [***]

5.9.2 Any disputes with respect to the findings of such auditor [***].

6. CONFIDENTIALITY; PUBLICATIONS, AND OTHER PUBLIC DISCLOSURES

6.1 Definition.

6.1.1 As used herein, a Party's "Confidential Information" means all confidential or proprietary Know-How and other information and materials related to the Licensed Compound or Licensed Products and disclosed under this Agreement by or on behalf of such Party or its Affiliates (such Party together with its Affiliates the "Disclosing Party") to the other Party or its Affiliates (such Party together with its Affiliates, the "Receiving Party") in written, graphical, physical, electronic, oral or any other form. For the avoidance of doubt: Bayer's Confidential Information includes the Licensed Know-How and any unpublished Licensed Patent Right.

6.1.2 Further, the terms and conditions of this Agreement shall be deemed both Parties' Confidential Information hereunder and, with regard thereto, both Parties shall be subject to the obligations of confidentiality and non-use as per this Section 6.

6.1.3 Confidential Information does not include information which the Receiving Party can prove:

(a) is at the time of disclosure part of the public domain or becomes thereafter part of the public domain other than by an unauthorized disclosure of the Receiving Party in breach of this Agreement; for the sake of clarity, information shall not be deemed to be in, or have come into, the public domain merely because any part of such information is embodied in general information which is or becomes publicly known or because individual features, components or combinations thereof are or become publicly known;

(b) has been obtained by the Receiving Party from a Third Party prior to or after its disclosure by the Disclosing Party, as documented by the Receiving Party's business records; provided that such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party under an obligation of confidentiality; or

(c) was developed by or on behalf of the Receiving Party independently of the Confidential Information provided by the Disclosing Party, as documented by the Receiving Party's business records, and without breach of the terms of this Agreement.

Notwithstanding any provision to the contrary set forth in this Agreement, during the Term, all Licensed Know-How and unpublished Licensed Patent Rights, in each case, that is specific or directly related to the Licensed Compounds or the Licensed Products will be Confidential Information of both Parties and, for clarity, all other Licensed Know-How and unpublished Licensed Patent Rights will be Confidential Information of Bayer solely; provided that Bayer shall not be restricted in disclosing Licensed Know-How to any Third Party licensee in a country of the Territory in which the exclusive license granted to Licensee hereunder has expired or become non-exclusive, provided that such Third Party licensee is bound by a contractual obligation of confidentiality and non-use at least as restrictive as set forth in this Agreement.

6.2 Protection of Disclosing Party's Confidential Information; Public Disclosure

6.2.1 *Obligation of Confidentiality and Non-Use*. Each Party agrees, with regard to Confidential Information received from the Disclosing Party, that during the Term and for a period of [***] thereafter it shall:

(i) keep such Confidential Information strictly confidential and reasonably protected against disclosure;

(ii) not use the Confidential Information, for any purposes other than those expressly permitted under this Agreement; and

(iii) not disclose Confidential Information to any person or entity other than as permitted by Section 6.2.3 and Section 6.4.

6.2.2 In case of concern relating to the other Party's technical and organizational measures for the protection of Confidential Information (including suspicion of, or actual, loss or leakage of the requesting Party's Confidential Information), a Party shall have the right upon [***] prior notice and during regular business hours of the other Party to :

(i) request the disclosure of such other Party's self-reported information for the requesting Party's review; and

(ii) have calls/video meetings with the other Party's relevant personnel that such other Party makes available to respond to the requesting Party's questions, provided that such right may not be exercised in a manner that interferes with the normal operations and activities of such other Party's personnel.

6.2.3 *Exceptions from the Obligation of Confidentiality and Non-Use*. A Receiving Party may disclose Confidential Information disclosed to it as follows:

(i) Confidential Information may be disclosed to the following persons and entities if such have a need to know and are bound by an obligation (contractual, fiduciary or otherwise) of confidentiality, non-use and non-disclosure at least as restrictive as set forth herein: (a) the Receiving Party's and its Affiliates' officers, directors and employees; (b) any Third Party to the extent reasonably necessary or appropriate to exercise the Receiving Party's rights or perform the Receiving Party's obligations under this Agreement, including, solely in the case of Licensee as the Receiving Party, to subcontractors and Sublicensees; and (c) *bona fide* actual or prospective: investors, investment bankers, lenders, other financing sources for the purpose of Licensee's financing, merger partners, acquirers of a Party or substantially all of its assets referring to the Licensed Compound and all Licensed Products; provided that, in each case (a) – (c), the Receiving Party shall remain responsible for any failure by any person who receives Confidential Information pursuant to this Section 6.2.3(i)

(ii) Confidential Information may be disclosed (a) in the case of either Party as the Receiving Party, to Governmental Authorities in order to obtain, maintain or defend Patent Rights as permitted under Section 9 and (b) solely in the case of Licensee as the Receiving Party, to Regulatory Authorities or other governmental authorities to seek and obtain approval to conduct clinical trials, file, obtain and maintain Marketing Approval or Pricing Approval with respect to a Licensed Product and to otherwise Exploit the Licensed Compounds and Licensed Products, provided, however, that Licensee shall be obliged to take reasonably diligent efforts to adequately protect Bayer's Confidential Information in any clinical trial applications and any other submission to Regulatory Authorities or other governmental authorities.

(iii) Confidential Information may be disclosed if and only to the extent such disclosure is required by Laws (for clarity, including (a) as required pursuant to a validly issued request for information from a Regulatory Authority and (b) as required pursuant to the rules and regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange of listing entity); provided that and without limiting clause (ii) above, [***], but in any case, if reasonably possible, not later than [***] prior to any such disclosure, to the extent permitted by Laws, the Receiving Party shall notify the Disclosing Party and give reasonable opportunity to review and comment on the proposed disclosure and/or seek a protective order or other appropriate remedy and the Receiving Party shall consider in good faith any comments timely provided by the Disclosing Party. To the fullest extent permitted by Laws, the Receiving Party shall seek confidential treatment of any Confidential Information disclosed to it under this Section 6.2.3(iii).

6.3 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Section 6 shall supersede any prior non-disclosure, secrecy or confidentiality agreement(s) between the Parties (and/or their Affiliates) dealing with the subject matter of this Agreement, including the Confidentiality Agreement. Any confidential information disclosed under such Confidentiality Agreement and dealing with the subject of this Agreement shall be deemed disclosed under this Agreement.

6.4 Publications, Press Releases, and Other Public Disclosure. Notwithstanding any provision to the contrary set forth in this Agreement:

6.4.1 Except as otherwise required by Laws, neither Party shall issue a press release or make any other public disclosure concerning the terms and conditions of this Agreement (including the Effective Date and maximum financial obligations) without the prior written approval of such press release or public disclosure by the other Party, which shall not be unreasonably withheld, conditioned or delayed.

6.4.2 For any press release or public disclosure concerning the terms and conditions of this Agreement, the following shall apply.

(i) Each Party shall submit the content proposed for inclusion in any such press release or other public disclosure to the other Party for review and comment no less than [***] prior to the anticipated date of publication. The Parties shall cooperate in good faith to address any comments, concerns or objections within such period. After the applicable content in such press release or other public disclosure has been approved by the reviewing Party, it shall not be modified, altered, amended or adjusted in any material way by the publishing Party. The contents of any press release or other public disclosure that has been reviewed and approved by the reviewing Party can be re-released by either Party without a requirement for re-approval by the original reviewing Party.

(ii) The principles to be observed by Bayer and Licensee in such press releases and other public disclosures with respect to this Agreement shall be: accuracy, compliance with Laws, and the requirements of confidentiality under this Section 6. Notwithstanding the foregoing, either Party may issue a press releases or other public disclosure as it determines, based on advice of counsel, are reasonably necessary to comply with Laws or for appropriate market disclosure in accordance with the terms of Section 6.2.3(iii).

6.4.3 Public disclosure regarding data, information or results related to the Licensed Compounds or the Licensed Products.

6.4.3.1 *By Licensee*. Subject to Section 6.4.3.2 and Section 6.4.4, Licensee shall have the exclusive right to, at its sole discretion and without Bayer's written consent, publicly disclose (including through a public announcement, press release, or Publication) any data, information or results related to the Licensed Compounds or the Licensed Products; provided that, for any Publication,, Licensee allows Bayer to review and comment in accordance with Section 6.4.3.3.

6.4.3.2 *By Bayer*. Bayer shall have the right, but not the obligation, to make Publications on the Development work completed by Bayer prior to the Effective Date; [***], and subject to the procedure and the Parties' compliance with Section 6.4.3.3; provided, further, that for any such Publication related to [***], Bayer shall also share a preliminary draft with Licensee as far in advance of Bayer's intended submission as reasonably practicable, and the Parties shall cooperate in good faith to address any comments, concerns or objections of Licensee on the draft.

6.4.3.3 *Good faith cooperation*. Each Party shall send the other Party any planned Publication for review no later than [***] before submission for publication or presentation. The other (reviewing) Party may provide comments within [***] of its receipt of such written copy, and the Parties shall cooperate in good faith to address any comments, concerns or objections prior to submission. The Parties will comply with International Committee of Medical Journal Editors standards regarding authorship and contributions for each such publication or presentation.

6.4.4 Clinical Trial Transparency. Bayer shall have the right to disclose to the EU Clinical Trials Register and to publish on its internet page a summary of the results of [***] and a plain language summary in accordance with existing industry commitments as announced in the "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" by EFPIA, PhRMA, JPMA and IFPMA on January 6th 2005 and effective as of Jan 6th, 2005 (as amended from time to time), and in accordance with Bayer's Clinical Trial Transparency Policy (https://clinicaltrials.bayer.com/transparency-policy/); *provided* that Bayer shall not make such disclosure prior to the earlier of [***]. At least [***] before Bayer makes a disclosure under this Section 6.4.4, Bayer shall send a final draft of the information to be published to Licensee for review to be reasonably considered by Bayer so long as such comments are in compliance with Laws, with the above-mentioned industry commitments, Bayer's Clinical Trial Transparency Policy and the International Committee of Medical Journal Editors (ICMJE) guidelines. If no comment by Licensee is received within [***] after Licensee having received the information to be published, Bayer shall be free to make the disclosure.

7. MANUFACTURE AND SUPPLY

7.1 Responsibility for Manufacturing and Supply.

7.1.1 Responsibility. Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible for and bear all costs of the manufacture and supply of the Licensed Product(s) in the Field in the Territory.

7.1.2 [***]

7.2 Manufacturing Technology Transfer and Assistance.

(i) Within the time periods specified in Exhibit 7.2, Bayer shall, [***], deliver to the Licensee the information and materials relating to the manufacturing process of the API and Licensed Product as specified in Exhibit 7.2. During the Transfer Period as defined in Exhibit 7.2, [***], Bayer shall provide Licensee with such Know-How (which, for clarity, constitutes Licensed Know-How) in a manner consistent with that specified in Exhibit 7.2 for similar Licensed Know-How. [***].

(ii) [***]

8. REPRESENTATIONS AND WARRANTIES

8.1 Bayer. As of the Effective Date, Bayer represents and warrants that:

[***]

[***]

[***]

[***]

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8.2 Licensee. As of the Effective Date, Licensee represents and warrants that:

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8.3 [***]

8.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO PATENT RIGHTS, KNOW-HOW, MATERIALS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. WITHOUT LIMITING SECTION 10.1, BAYER SHALL HAVE NO LIABILITY WHATSOEVER TO LICENSEE OR ANY OTHER PERSON FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED ON LICENSEE OR ANY OTHER PERSON, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM (A) THE PRODUCTION, USE, OR SALE OF ANY LICENSED PRODUCT, OR THE PRACTICE OF THE LICENSED PATENT RIGHTS; (B) THE USE OF ANY LICENSED KNOW-HOW; OR (C) THE USE OF ANY MATERIAL SUPPLIED HEREUNDER, IN EACH CASE ((A) AND (B)), BY ANY LICENSEE PARTY AFTER THE EFFECTIVE DATE.

9. INTELLECTUAL PROPERTY

9.1 Ownership

As between the Parties, (i) Bayer shall retain all right, title and interest in and to, and shall solely own, all Licensed Technology; and (ii) Licensee shall solely own all Know-How solely generated by Licensee's, its Affiliates' or its Sublicensees' employees, agents, representatives, contractors or consultants in the exercise of the rights granted to Licensee under this Agreement (together with all Patent Rights claiming such Know-How).

9.2 Patent Prosecution and Maintenance of Licensed Patent Rights A.

9.2.1 Licensed Patent Rights A. Licensee shall be responsible for the filing, prosecution and maintenance (including by way of patent term extensions such as supplementary protection certificates, pediatric extensions, and any other extensions that are now or become available in the future, wherever applicable) of the Licensed Patent Rights A [***]. Licensee shall (a) keep Bayer reasonably and timely informed as to the filing, prosecution and maintenance of any Licensed Patent Rights A, including the status thereof, and provide to Bayer copies of all material correspondence to or from any patent office related thereto including copies of any documents from any patent office important for any action to be taken related to the filing, prosecution and maintenance; (b) provide Bayer with copies of any material communications intended for submission to any patent office, including any divisional, continuation or continuation-in-part patent application of any Licensed Patent Right A with reasonable time – [***] - to review and comment prior to such submission; (c) furnish to Bayer copies of all documents related to any filing, prosecution and maintenance of such Licensed Patent Rights A, including a copy of each patent application or other submission as filed, together with notice of its filing date and serial number; and (d) incorporate reasonable and timely comments of Bayer on documents to be filed with any patent office that would affect Bayer's rights in such Licensed Patent Rights A hereunder. Bayer shall provide prompt and reasonable assistance with respect to the preparation, filing, prosecution and/or maintenance of Licensed Patent Rights A, as requested by Licensee and at Licensee's cost and expense, including by providing documentation and declarations that are reasonably required or useful for filing patent term extensions.

9.2.2 [***].

9.2.3 [***].

9.3 Patent Prosecution and Maintenance of Licensed Patent Right B

9.3.1 Licensed Patent Rights B. Bayer shall be responsible, at its sole discretion subject to Section 9.3.2, for the filing, prosecution and maintenance (including by way of patent term extensions such as supplementary protection certificates, pediatric extensions, and any other extensions that are now or become available in the future, wherever applicable) of the Licensed Patent Rights B [***]. Bayer shall (a) keep Licensee reasonably and timely informed as to the filing, prosecution and maintenance of any Licensed Patent Rights B, including the status thereof, and provide to Licensee copies of all material correspondence to or from any patent office related thereto including copies of any documents from any patent office important for any action to be taken related to the filing, prosecution and maintenance; (b) provide Licensee with copies of any material communications intended for submission to any patent office, including any divisional, continuation or continuation-in-part patent application of any Licensed Patent Right B with reasonable time – [***] - to review and comment prior to such submission; (c) furnish to Licensee copies of all documents related to any filing, prosecution and maintenance of such Licensed Patent Rights B, including a copy of each patent application or other submission as filed, together with notice of its filing date and serial number; and (d) incorporate reasonable and timely comments of Licensee on documents to be filed with any patent office. Licensee shall provide prompt and reasonable assistance with respect to the preparation, filing, prosecution and/or maintenance of Licensed Patent Rights B, as requested by Bayer and at Bayer's cost and expense, including by providing documentation and declarations that are reasonably required or useful for filing patent term extensions.

9.3.2 [***].

9.3.3 [***].

9.3.4 [***].

9.4 Patent Term Extension. [***].

9.5 Patent Enforcement of Licensed Patent Rights.

9.5.1 Notification of Infringement. If any Licensed Patent Right is or might be infringed by a Third Party, the Party first having knowledge thereof shall promptly notify the other Party in writing. Such notice shall set forth the facts of the infringement in reasonable detail and to the extent known by the notifying Party. Neither Party shall notify a Third Party of the infringement of a Licensed Patent Right without the written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. The Parties shall use reasonable efforts and cooperation to terminate the infringement of a Licensed Patent Right without litigation.

9.5.2 Enforcement of Licensed Patent Rights in the event of unexpired patent claims of Licensed Patent Rights B.

9.5.2.1 Bayer Right to Enforce. [***]

9.5.2.2 Licensee Right to Enforce. [***]

9.5.3 Enforcement of Licensed Patent Rights A in the Event of expired patent claims of Licensed Patent Right B.

9.5.3.1 Licensee Right to Enforce. [***]

9.5.3.2 Bayer Right to Enforce. [***]

9.5.4 Hatch Waxman.

9.5.4.1 Notice. If either Party receives any application, submission or notice under Section 505(b)(3) or 505(j)(2)(B) of the FD&C Act (e.g., the filing of an ANDA under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Licensed Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(IV), respectively), or otherwise becomes aware of the submission to a Regulatory Authority of an application for a product referencing a Licensed Product, it shall promptly notify the other Party in writing to that effect and provide a copy of such communication.

9.5.4.2 Enforcement.

(a) [***]

(b) [***]

(c) [***]

9.5.4.3 Cooperation. [***]

9.5.5 Third Party Actions. Each Party will immediately notify the other Party in the event that a Third Party Action is brought against any of the Licensed Patent Rights by a Third Party. [***]

9.5.6 Recovery. [***]

9.5.7 Cooperation. Each Party agrees to cooperate in any action under this Section 9 which is controlled by the other Party.

9.5.8 Settlement. [***]

9.6 Infringement of Third Party Patent Rights. If a Party becomes aware that a Third Party is asserting that a Patent Right or other intangible intellectual property right owned by it is infringed by a Licensed Compound or Licensed Product in the Field in the Territory, such Party shall promptly notify the other Party in writing setting forth the facts of such claim in reasonable detail and to the extent known by the notifying Party. In such a case, subject to Sections 10.1 and 10.3 of this Agreement, [***].

9.7 [***]

10. INDEMNIFICATION / LIMITATION OF LIABILITY

10.1 Bayer. Bayer shall indemnify, defend and hold harmless Licensee, its Affiliates and their respective directors, officers, employees and agents (each a "Licensee Indemnitee") from and against all liabilities, damages, expenses and losses, including reasonable attorneys' fees (collectively, "Losses") to which any Licensee Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party ("Third Party Claim") to the extent such Losses arise out of or relate to [***].

10.2 Licensee. Licensee shall indemnify, defend and hold harmless Bayer, its Affiliates and their directors, officers, employees and agents (each a "Bayer Indemnitee") from and against all Losses to which a Bayer Indemnitee may become subject as a result of any Third Party Claim to the extent such Losses arise out of or related to: [***].

10.3 Claims for Indemnification.

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10.3.6 [***].

10.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, OR LOST PROFITS, LOST REVENUE OR LOST GOODWILL, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE, [***].

10.5 Insurance. Each Party shall, during the Term, at its sole cost, obtain, carry and keep in force insurance with a reputable, solvent insurer in an amount as is appropriate in accordance with sound business practice and such Party' obligations under this Agreement. In lieu of the insurance coverage described in the preceding subsection, Bayer shall have the right to undertake self-insurance to cover its obligations hereunder, with financial protection comparable to that arranged by it for its own protection with regard to other products in its portfolio.

11. TERM AND TERMINATION

11.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article 11, shall continue in full force and effect on a country-by-country and Licensed Product-by-Licensed Product basis until the expiration of the Royalty Term for such Licensed Product in such country, with this Agreement expiring in its entirety upon the expiration of the Royalty Term for the last Licensed Product under this Agreement in the last country (the "Term"). Upon the expiration of the Royalty Term for a particular Licensed Product in a particular country, the license to Licensee in Section 2.1 with respect to such Licensed Product in such country shall be deemed fully-paid, royalty-free, perpetual, non-exclusive, and irrevocable.

11.2 Termination for Convenience. Licensee shall have the right to terminate this Agreement in its entirety for any reason (i) upon [***] prior written notice if such notice is made before the First Commercial Sale or (ii) upon [***] prior written notice if such notice is made on or after the First Commercial Sale.

11.3 Termination for Material Breach. Breach by Licensee or Bayer of any of its respective material obligations under this Agreement (including, for clarity, Licensee's obligations under Section 3.2.1) shall entitle the other non-breaching Party to give such Party in breach written notice (a "Breach Notice") requiring it to cure such breach. If the breach is capable of being cured, but cure of such breach cannot reasonably be effected within [***] upon receipt of the Breach Notice, the breaching Party shall deliver to the non-breaching Party a plan (a "Cure Plan") reasonably calculated to cure such breach within a reasonable timeframe, but in any event within [***] from receipt of the Breach Notice. So long as the breaching Party is diligently carrying out such Cure Plan, the non-breaching Party shall not have the right to terminate this Agreement pursuant to this Section 11.3. If the breaching Party fails to cure such breach within [***] or diligently carry out such Cure Plan and cure such breach within [***], as applicable, then the non-breaching Party may terminate this Agreement upon written notice to the breaching Party. The right of either Party to terminate this Agreement as herein above provided shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous breach.

11.4 Termination for Insolvency. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within [***] after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within [***] thereafter, the other Party, may immediately terminate this Agreement effective upon notice of such termination.

11.5 Termination for Patent Challenge. If, during the Term, Licensee or one of its Affiliates or Sublicensees commences or participates in, or actively assists any other Person in bringing, any challenge to the validity, patentability or enforceability of a Valid Claim of any of the Licensed Patent Rights Covering a Licensed Compound or Licensed Product (a "Patent Challenge"), then, Bayer will have the right to terminate this Agreement in its entirety upon [***] prior written notice to Licensee unless Licensee, such Affiliate or such Sublicensee causes such Patent Challenge to be withdrawn within such [***] period following receipt of written notice from Bayer (or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges in which Licensee or its Affiliate or Sublicensee does not have the power to unilaterally cause the Patent Challenge(s) to be withdrawn, Licensee or its Affiliate or Sublicensee withdraws as a party from such Patent Challenge(s) and ceases actively assisting any other party to such Patent Challenge(s) within such [***] period). The foregoing sentence will not apply with respect to any Patent Challenge that is first made by Licensee or one of its Affiliates or Sublicensees in defense of a claim of patent infringement brought by Bayer under the applicable Licensed Patent Rights at issue under such Patent Challenge. [***].

11.6 General Effects of Termination and Expiration.

11.6.1 In case of any termination in its entirety or expiration of this Agreement, all rights and obligations of the Parties shall cease immediately, unless otherwise indicated in this Agreement.

11.6.2 Expiration or termination in its entirety of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be entitled to injunctive relief as a remedy for any such breach.

11.6.3 Upon termination in its entirety or expiration of this Agreement, upon the request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or destroy the Disclosing Party's Confidential Information, including all copies thereof, except to the extent that retention of such Confidential Information is reasonably necessary for the Receiving Party to Exploit any continuing rights it may have and/or to fulfill its obligations contemplated herein, including one copy of the Confidential Information stored in a secure place for the sole purpose of evidence. The return and/or destruction of such Confidential Information as provided above shall not relieve the Receiving Party of its obligations under this Agreement. The provisions of this section shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Party according to provisions of Law.

11.6.4 Termination by Licensee under Section 11.2 or by Bayer under Section 11.3, 11.4 or 11.5. Exept as otherwise provided in this Section 11.6.4, the following provisions shall apply if Licensee terminates this Agreement pursuant to Section 11.2 or if Bayer terminates this Agreement pursuant to Section 11.3, 11.4 or 11.5.

(a) Licensee shall grant, and hereby does grant, to Bayer, effective as of the effective date of such termination, an exclusive, royalty-free, sublicensable, through multiple tiers of sublicensees, license under the Reversion Technology to Develop, Manufacture and Commercialize the Reversion Products in the Field in the Territory; [***].

(b) As promptly as practicable (and in any event within [***]) after the effective date of such termination, to the extent permitted by applicable Law, Licensee shall [***]: (i) deliver to Bayer or its designee true, correct and complete copies of all regulatory submissions, filings, registrations and approvals (including NDAs and Marketing Authorizations) for any Reversion Product owned or Controlled by Licensee, any of its Affiliates or, subject to Section 11.6.4(f), Sublicensees; (ii) transfer or assign, or cause to be transferred or assigned, to Bayer or its designee (or to the extent not so assignable, take all reasonable actions to make available to Bayer or its designee the benefits of) all regulatory submissions, filings, registrations and approvals (including NDAs and Marketing Authorizations) for any Reversion Product owned or Controlled by Licensee, any of its Affiliates or, subject to Section 11.6.4(f), Sublicensees; (iii) transfer, or cause to be transferred, to Bayer or its designee all data, reports, records, written materials and information, owned or Controlled by Licensee, any of its Affiliates or, subject to Section 11.6.4(f), Sublicensees to the extent that such data, reports, records, written materials or other information solely relates to the Reversion Product and is included within the Reversion Technology licensed to Bayer under Section 11.6.4(a); and (iv) take such other actions and execute such other instruments, assignments and documents as may be reasonably necessary to effect, evidence, register and record the transfer, assignment or other conveyance to Bayer or its designee of rights under this Section 11.6.4(b). Further, for a period of [***] after the date of such transfer, Licensee shall, or cause its Affiliates to, provide assistance to Bayer or its designee as reasonably necessary for the technical enablement of the Reversion Technology, [***].

(c) Licensee shall, as directed by Bayer, either (i) wind-down any ongoing clinical Development activities (including clinical trials) with respect to any Reversion Product in an orderly fashion or (ii) promptly transition ongoing Development activities to Bayer or its designee, in each case ((i) and (ii)), with due regard for patient safety and in compliance with all Laws. [***].

(d) If this Agreement is terminated prior to a First Commercial Sale of a Licensed Product, (i) Bayer (or a designee as nominated by Bayer) shall have the right, but not the obligation, to purchase from Licensee any or all usable clinical inventory of any Reversion Product in Licensee's or its Affiliates' possession as of the effective date of such termination, [***], and (ii) Licensee will use Commercially Reasonable Efforts to cause any terminated Sublicensee to offer to Bayer (or a designee as nominated by Bayer) for purchase any or all usable clinical inventory of any Reversion Product in such Sublicensee's possession as of the effective date of such termination [***].

(e) If this Agreement is terminated after to a First Commercial Sale of a Licensed Product:

(i) in case Licensee or any of its Affiliates or Sublicensees is then selling any Licensed Products, Licensee, its Affiliates and its Sublicensees shall have the right to sell any inventory of such Licensed Products intended for Commercialization in the Territory existing as of the effective date of such termination for up to [***] after the effective date of such termination (the "Commercialization Wind-Down Period"), [***].

(ii) Any Licensed Product sold or disposed of by Licensee, its Affiliates or its Sublicensees in the Territory during the Commercialization Wind-Down Period under Section 11.6.4(e)(i) shall be subject to all obligations by Licensee applicable to sales of Licensed Products under the Agreement, including the consideration, payment and reporting obligations under Section 4 (Consideration) and Section 5 (Payments) and all related rights by Bayer including the right to audit under Section 5.9.

(f) Survival of Sublicenses. [***]

11.7 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination and which by their very nature are intended to survive. Without limiting the provisions of Section 11.6 (and any Sections referenced therein), the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: 1, 3.6 (for any period after the Term required by applicable Law), 5.8, 5.9 (for the period after the Term specified therein), 6.1, 6.2, 8.4, 9.1, 9.5.6 (solely for purposes of any recovery accrued as of the date of expiration or termination but not yet paid to the Parties per the terms of such Section 9.5.6), 10, 11.1 sentence 2, this Section 11.7, 12, and 14 of this Agreement.

12. DISPUTE RESOLUTION

12.1 Dispute Resolution. The Parties shall try to settle any dispute, controversy or claim that arises out of, or relates to, this Agreement or the breach, termination or validity thereof (a "Disputed Matter") by first referring the Disputed Matter to the Parties' Executive Sponsors who shall meet within [***] of the Disputed Matter being referred to them (in person, by means of telephone conference, videoconference or other means of communications) and attempt in good faith to resolve such Disputed Matter [***]. All such discussions shall be confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. Notwithstanding the foregoing, if such Executive Sponsors cannot resolve such Disputed Matter within [***] after their first meeting for such negotiations, then, either Party may pursue the remedies set forth in Section 12.2 to 12.4.

12.2 Arbitration. Subject to Sections 12.3 and 12.4 below, any Disputed Matter which cannot be resolved pursuant to Section 12.1, shall be finally settled under the Rules of Arbitration of the ICC (the "Rules") in effect at the time of submission, as modified by this Section 12.2. The arbitration will be heard and determined by a panel of three (3) arbitrators. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [***] following appointment of the second arbitrator, by the ICC. The place of arbitration shall be New York, NY, United States and the language to be used in any such proceeding (and for all testimony, evidence and written documentation) shall be English. The IBA Rules on the Taking of Evidence in International Arbitration shall apply on any evidence to be taken up in the arbitration. The arbitration award so given shall, absent manifest error, be a final and binding determination of the Disputed Matter, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 10.4 (if not invalid by Law) (Limitation of Liability). Except in a proceeding to enforce the results of the arbitration or as otherwise required by applicable Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties.

12.3 Disputes Related to Patent Rights. Without prejudice to the generality of Section 12.2, either Party may bring an action in any court or administrative agency of competent jurisdiction to resolve disputes solely pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patent Rights, and no such claim shall be subject to arbitration pursuant to Section 12.2.

12.4 Injunctive Relief. Nothing contained in this Agreement shall deny either Party the right to seek preliminary injunctions or other interim or provisional relief from a court of competent jurisdiction in the context of a breach or threatened breach of any provision of this Agreement.

13. DATA PRIVACY

13.1 Each Party shall perform, and shall ensure that its Affiliates and Sublicensees perform, its obligations under this Agreement in accordance with applicable data protection Laws, including the General Data Protection Regulation EU 2016/679 ("GDPR").

13.2 Data privacy related terms shall have the meaning as defined in Art. 4 of the GDPR if not otherwise defined in this Agreement.

13.3 The Parties acknowledge that they will need to process "personal data" (within the meaning of Art. 4 of the GDPR) of the respective other Party's employees ("Employee Data") for the purpose of managing their contractual relationship.

13.4 In the context of this Agreement, a Party may also need to transfer Development related data (including information about health) on an individual person level to the respective other Party. Such data (including from Clinical Trials) may qualify as "personal data" within the meaning of Art. 4 GDPR (such data qualifying as "personal data" hereinafter the "Human Data").

13.5 Where a Party discloses Human Data to the respective other Party, the disclosing Party is responsible to ensure meeting all conditions that are legally required to allow this disclosure for purposes of this Agreement (including medical and diagnostic Development purposes). This may include e.g., ensuring that respective data subjects have given and not withdrawn their consents, or anonymizing or de-identifying Human Data prior to disclosure (examples not exhaustive).

13.6 For the purposes of the GDPR, the Parties agree that each of Bayer and Licensee are independent controllers with respect to the personal data shared under this Agreement as set out in Sections 13.3 and 13.4.

13.7 With respect to transfer of personal data subject to the GDPR, including Employee Data and Human Data, from Bayer to Licensee, the Parties hereby enter the standard contractual clauses (module 1) published in the Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679, as attached in Exhibit 13.7. In the event that a change in applicable data protection Laws would require a different transfer mechanism than standard contractual clauses or that the European Commission agrees on amended standard contractual clauses which require other specifications than the ones provided above, Bayer and Licensee shall cooperate in good faith to implement such an alternative prior to the effective date of the integration of the new requirements.

13.8 Each Party confirms that at time of signature of this Agreement, it is not aware of any legal requirement that hinders disclosing Human Data to the respective other Party as required to fulfill the obligations under this Agreement.

13.9 The Party disclosing Human Data to the other Party shall do so only encrypted or via secure communication channels.

13.10 The Party receiving Employee Data and Human Data from the respective other Party may only use those as required for purposes of this Agreement.

13.11 The receiving Party is responsible to meet applicable data protection Laws when using received Human Data, including the GDPR.

13.12 Where Human Data are anonymized, pseudonomized or de-identified, the receiving Party shall refrain from any attempt to identify the data subject of the Human Data. This includes that Human Data shall not be supplemented or combined with any information which de-facto allows for a re-identification.

13.13 The receiving Party shall implement appropriate technical and organizational measures to protect the Human Data against accidental or unlawful destruction or loss, alteration, unauthorized disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected. This includes restricting access to Human Data to a need-to-know level.

13.14 Each Party shall provide the other with such assistance as may be reasonably requested to ensure that each Party complies with their obligations under applicable data protection Laws. For clarity, such assistance may include cooperating in response to requests from data subjects or supervisory authorities, cooperating in connection with the conduct of data protection impact assessments, and the provision of information to data subjects relating to the personal data processing.

13.15 Each Party shall notify the other without undue delay in the event that it becomes aware of a breach of applicable data protection Laws in the context of activities related to this Agreement or of a change in applicable data protection Laws that is likely to have a material adverse effect on any Party's compliance with this Section 13.

14. MISCELLANEOUS

14.1 Interpretation.

14.1.1 The headings of sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

14.1.2 All references in this Agreement to the singular shall include the plural where applicable.

14.1.3 The use of any gender is applicable to all genders.

14.1.4 Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such section, and references in this Agreement to any subsection shall include all paragraphs in such subsection.

14.1.5 Any list or examples following the word “including” shall be interpreted without prejudice to the generality of the preceding words.

14.1.6 The word “will” will be construed to have the same meaning and effect as the word “shall.

14.1.7 The word “or” means “and/or” unless the context dictates otherwise because the subjects of the conjunction are or intended to be mutually exclusive.

14.1.8 The words “herein,” “hereof,” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular section or other subdivision.

14.1.9 All references to days or years in this Agreement shall mean calendar days or calendar years, as the case may be, unless otherwise specified.

14.1.10 References herein to any law or regulation are to such law or regulation as amended, modified, codified, reenacted, supplemented or superseded in whole or in part, and in effect from time to time.

14.1.11 This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

14.2 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without giving effect to any choice or conflict of law provisions.

14.3 Independent Contractors. Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture or the relationship of principal and agent or employer and employee between the Parties. Neither Party shall enter into or have authority to enter into any engagement or make any representation, warranty or guarantee, express or implied, on behalf of the other Party or otherwise bind or oblige the other Party hereto. Each Party agrees to perform under this Agreement solely as independent contractor.

14.4 Assignment.

14.4.1 Subject to Sections (a)-(e) below, this Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, each of which such successors and permitted assigns will be deemed to be a Party hereto for all purposes hereof.

(a) No Party may assign or otherwise transfer either this Agreement or any of its rights, interests, or obligations hereunder without the prior written approval of the other Party. Any attempted assignment by Bayer or Licensee in violation of this Section 14.4.1 shall be null and void and of no legal effect.

(b) Notwithstanding clause (a) above, either Party, upon providing written notice to the other Party, may without the consent of such other Party, assign or otherwise transfer this Agreement or any right or obligation hereunder to one or more of its Affiliates, and so long as the assigning Party is not relieved of any liability accrued hereunder prior to such assignment hereunder.

(c) Notwithstanding clause (a) above, each Party (or its permitted successive assignees or transferees hereunder), upon providing the other Party prior written notice, may without the consent of the other Party, assign or transfer this Agreement as a whole to an entity that succeeds to all or substantially all of the business or assets of such Party related to the subject matter of this Agreement, so long as the assigning Party is not relieved of any obligation accrued hereunder prior to such assignment and such assignment is a Qualified Assignment.

For the purposes of this Agreement, a "Qualified Assignment" means any transaction that:

(i) is made in compliance with Laws, including securities, tax and corporation laws;

(ii) includes the assignee's written acknowledgement of and agreement to all of the assigning Party's obligations under the Agreement;

(iii) is made to an assignee that is, and will be after giving effect to the relevant assignment, Solvent;

For purposes of this Section 14.4.1, "Solvent" means, with respect to any person as on any date of determination, that as of such date, (i) the value of the assets of such Person is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (ii) such Person is able to pay all liabilities of such Person as such liabilities mature and (iii) such Person does not have unreasonably small capital (taking into account such Person's obligations hereunder). In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represent the amount that can reasonably be expected to become an actual or matured liability. In computing the value of the assets of a Person, the value shall be determined in the context of current facts and circumstances affecting such Person.

(iv) is made to an assignee that is not subject at the time of such assignment to any order, decree or petition providing for (A) the winding-up or liquidation of such Person, (B) the appointment of a receiver over the whole or part of the assets of such Person or (C) the bankruptcy or administration of such Person;

(v) is not a voidable fraudulent conveyance;

(vi) is made to an assignee that is at the time of such assignment not debarred under 21 U.S.C. §30 or under investigation or threatened to be debarred under 21 U.S.C. §30; and

(vii) will not cause a material increase in taxes, costs or expenses to the non-assigning Party (unless the assigning Party or the assignee has agreed to compensate the non-assigning Party for the same).

(d) Notwithstanding clause (a) above, each Party may at any time assign its rights, interests and obligations provided for hereunder to any Person by merger or with the prior written consent of the other Party.

(e) Notwithstanding clause (a) above, Bayer may assign its right to receive payments hereunder, in whole or in part and in their entirety or in portions, to a Third Party, without the written consent of Licensee, provided that Bayer shall provide reasonable (and at least [***]) prior written notice to Licensee before entering into any such transaction. Without limiting Bayer's notice obligation under the foregoing sentence, in the event Bayer closes any transaction effectuating any such assignment of such rights, Bayer agrees to further notify Licensee promptly after such assignment of the name and address of the assignee and the name, address, telephone number and email address, if any, of the individual employee of the assignee who shall be the initial contact person with respect to such payment obligations under this Agreement.

14.4.2 Notwithstanding anything to the contrary in Section 14.4.1 or elsewhere in this Agreement, Licensee may grant or permit any encumbrance on or assignment of all or part of its rights under this Agreement to any Person in connection with a financing for Licensee from time to time.

14.5 Compliance with Laws. Each Party shall perform, and shall ensure that its Affiliates perform, such Party's obligations under this Agreement in accordance with Laws.

14.6 Notices. Any notice required or permitted to be given under this Agreement by one Party to the other shall be in writing and delivered by facsimile or via a nationally-recognized overnight courier service with acknowledgement of receipt, and, in each case, addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee:

If to Licensee:	Pulmovant, Inc. [***]
With a copy to (which shall not constitute notice):	legalnotices@roivant.com
If to Bayer:	Bayer AG [***]
With a copy to (which shall not constitute notice):	Bayer AG [***]

This Section 14.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

14.7 Force Majeure. Neither Party shall be responsible or liable to the other Party for any failure to perform any of its obligations hereunder, if such failure results from circumstances beyond the control of such Party, including requisition by any governmental authority, wars, strikes, lockouts, riots, epidemic, pandemic, disease, an act of God, civil commotion, fire, earthquake, storm, failure of public utilities, common carriers or supplies, or any other circumstances similar to the above causes and whether or not foreseeable . Either Party affected by the force majeure event shall use reasonable efforts to avoid or remove any such cause and shall resume performance under this Agreement as soon as feasible whenever such cause is removed; provided that the foregoing shall not be construed to require such Party to settle any dispute with any Third Party, to commence, continue or settle any litigation, or to incur any unusual or extraordinary expenses. The Party affected by the force majeure event shall upon its occurrence promptly give written notice to the other Party specifying the nature of the event and its anticipated duration.

14.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise shall be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws.

14.9 Severability. If any provision of this Agreement shall be found to be invalid or otherwise unenforceable in whole or in part, the validity or enforceability of the remainder of this Agreement shall not be affected. Furthermore, the Parties agree that the invalid portion of an unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of this Agreement had they considered the issue concerned.

14.10 Waiver. Any term or condition of this Agreement may be waived only by a written instrument executed by the Party waiving the benefit of a right hereunder. The waiver by a Party of any right hereunder shall not be deemed a continuing waiver of such right or of another right hereunder, whether of a similar nature or otherwise.

14.11 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

14.12 Amendments. This Agreement (including the attached exhibit(s)) shall not be amended or otherwise modified without a written document signed by the duly authorized representative(s) of each Party.

14.13 Entire Agreement. This Agreement (including the attached exhibit(s)) contains the entire understanding of the Parties with respect to the subject matter hereof. All other express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made, including the Confidentiality Agreement, are expressly superseded by this Agreement.

14.14 Priorities. In the event of any ambiguity, doubt or conflict emerging herein, the terms and conditions of this Agreement shall take precedence over the terms and conditions of any exhibit, unless the latter makes an explicit reference to the provision of this Agreement that shall be amended.

14.15 Use of Name. Neither Party shall use the name or trademarks of the other Party, without the prior written consent of such other Party, except in connection with the disclosure of the existence of this Agreement. Notwithstanding the foregoing, each Party and its Affiliates may disclose on its website and the promotional materials therein that the other Party is a partner (licensee or licensor, as applicable) of such Party for the Licensed Compounds or Licensed Products and may use the other Party's name in conjunction with such disclosure.

14.16 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement

14.17 Expenses. [***]

14.18 Performance by Affiliates. Licensee may discharge any obligations and exercise any right hereunder through any of its Affiliates.

14.19 No Third Party Beneficiaries. Except as expressly set forth in this Agreement, there are no Third Party beneficiaries hereunder and the provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against either Party by reason of these provisions or be entitled to enforce any of these provisions against either Party.

14.20 Counterparts; Electronic Signatures and Electronic Delivery. This Agreement may be executed and delivered in any number of counterparts, each of which so executed and delivered shall be deemed to be an original and all of which shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or as scanned executed documents sent by electronic mail or by electronic signature, with such facsimile, scanned and electronic signatures having the same legal effect as original signatures.

[signature page to follow]

IN WITNESS WHEREOF, Bayer and Licensee have caused this Agreement to be executed and entered into by their respective duly authorized representatives as of the dates specified below.

Bayer Aktiengesellschaft

Date:

By: ppa. [***]

Print Name: [***]

Title: [***]

Date:

By: i.V. [***]

Print Name: [***]

Title: [***]

Pulmovant, Inc.

Date:

By: [***]

Print Name: [***]

Title: [***]

Exhibit 10.46

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.

AMENDMENT

TO THE

LICENSE AGREEMENT DATED JULY 27, 2023

THIS AMENDMENT (the "Amendment"), effective as of the date of the last signature (the "Amendment Effective Date"), is entered into by and between Bayer Aktiengesellschaft having a place of business at [***] ("Bayer") and Pulmovant, Inc., having a place of business at [***] ("Licensee"). Bayer and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

BACKGROUND

WHEREAS:

A. Bayer owns or Controls from its Affiliate Bayer Pharma AG certain patent rights, know-how and other intellectual property relating to [***] ([***]);

B. Licensee is a wholly-owned subsidiary of Roivant Sciences Ltd. which is experienced in the discovery, development, and commercialization of pharmaceutical products.

C. The Parties have entered into a License Agreement dated July 27, 2023 (the "Agreement") under which Licensee acquired an exclusive license under the Licensed Technology and under which Bayer agreed to provide certain samples and materials to Pulmovant;

D. [***]

NOW, THEREFORE, the Parties hereto agree, in accordance with Section 14.12 of the Agreement, as follows:

1. DEFINITIONS; COMING INTO FORCE

1.1 All defined terms used in this Amendment shall have the meaning ascribed to them in the License Agreement, unless expressly stated otherwise herein.

1.2 The provisions of this Amendment shall come into force on the Amendment Effective Date.

2. [***]

[***]

3. MISCELLANEOUS

3.1 All provisions of the Agreement not altered by this Amendment shall remain in force unaltered. All provisions of the Agreement altered by this Amendment shall only be altered as far as expressly stated in this Amendment.

3.2 The miscellaneous clauses as set out in Section 14 of the Agreement shall apply mutatis mutandis to this Amendment.

3.3 The Parties shall keep the terms of this Amendment confidential in accordance with Section 6.1.2 of the Agreement.

3.4 This Amendment shall be governed by, and construed and enforced in accordance with, the laws of New York as set out in Section 14.2 of the Agreement and the Parties agree to the dispute resolution process as set forth in Section 12.

3.5 This Amendment may be executed and delivered in any number of counterparts, each of which so executed and delivered shall be deemed to be an original and all of which shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or as scanned executed documents sent by electronic mail or by electronic signature, with such facsimile, scanned and electronic signatures having the same legal effect as original signatures.

[signature page to follow]

IN WITNESS WHEREOF, Bayer and Licensee have caused this Agreement to be executed and entered into by their respective duly authorized representatives as of the dates specified below.

Bayer Aktiengesellschaft

Date:

By: ppa. [***]

Print Name: [***]

Title: [***]

Date:

By: i.V. [***]

Print Name: [***]

Title: [***]

Pulmovant, Inc.

Date:

By: [***]

Print Name: [***]

Title: [***]

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 12, 2024

/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 12, 2024

/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, 2024, 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 12, 2024

/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, 2024, 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 12, 2024

/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.