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 June 30, 2025
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 August 6, 2025, the registrant had 682,881,743 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 prospects.
- 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.
- Immunovant relies on the HanAll Agreement to provide the rights to the core intellectual property relating to IMVT-1402 and batoclimab. Any termination or loss of significant rights under the HanAll Agreement would adversely affect Immunovant's development and commercialization of IMVT-1402 and batoclimab.
- We will likely incur significant operating losses for the foreseeable future and may never achieve sustained profitability.
- 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 acquisitions, divestitures and other strategic transactions.
- We face risks associated with the use of our cash, cash equivalents and marketable securities.
- We are exposed to risks related to our significant holdings of cash, cash equivalents and marketable securities.
- While we do not have a need for additional capital under our current operating plans as a result of our current liquidity position, we may in the future require additional capital to fund our operations. In that case, if we fail to obtain necessary financing when needed, we may not be able to successfully acquire or in-license new product candidates, complete the development and commercialization of our product candidates following regulatory approval and continue to pursue our drug discovery efforts.
- Our business strategy and potential for future growth relies on a number of assumptions, some or all of which may not be realized.
- Our drug discovery efforts may not be successful in identifying new product candidates.
- Unfavorable, uncertain and rapidly changing global and regional economic, political and public health conditions could adversely affect our business, financial condition or results of operations.
- A portion of our or certain of our Vants' manufacturing, laboratory research or clinical trial activities takes place in Asia. A significant disruption in that region, such as a trade war or political unrest, could materially adversely affect our business, financial condition and results of operations.

- Inadequate funding for the FDA, U.S. Patent and Trademark Office ("USPTO"), SEC or other government agencies could hinder, delay or result in the suspension of those agencies' operations, which could harm our business.
- 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, preliminary or top-line 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.
- Changes in methods of product manufacturing or formulation may result in additional costs or delays.
- Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulatory authority may delay, limit or deny approval. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized. If we are unable to obtain regulatory approval in one or more jurisdictions for any product candidate, 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 undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit the scope of any approved label or market acceptance following regulatory approval or result in significant negative consequences.
- 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.
- 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 do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of our product candidates.
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- The use of artificial intelligence ("AI") could expose us to liability or adversely affect our business.
- 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 own or have in-licensed with respect to our product candidates fail to issue, if their validity, patentability, enforceability, 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.

- 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 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.
- 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 businesses;
- our Vant structure;
- potential future payments we may owe in connection wth our product candidates;
- acquisitions, divestitures and other strategic transactions;
- the use of our cash, cash equivalents and marketable securities;
- the potential future need for additional capital to fund our operations;
- clinical trials and preclinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- unfavorable, uncertain and rapidly changing global and regional economic, political and public health conditions;
- the fact that designing and implement clinical trials and preclinical studies is very expensive, time-consuming and difficult;
- difficulties we may encounter enrolling and retaining patients in clinical trials, which could adversely affect or otherwise delay clinical development activities;
- the results of our preclinical studies and clinical trials not supporting our proposed claims for a product candidate or regulatory approval;
- interim, preliminary or top-line data from our clinical trials changing as more data become available or data being delayed due to audit or verification procedures;
- changes in product candidate manufacturing or formulation that could result in additional costs or delays;

- the fact that obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process and the FDA or another regulatory authority may delay, limit or deny approval;
- the failure of our clinical trials to demonstrate substantial evidence of the safety and efficacy of our product candidates;
- undesirable side effects caused by our product candidates that halt their clinical development, delay or prevent their regulatory approval, limit the scope of any approved label or market acceptance or result in negative consequences;
- 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;
- the failure of any third-party we rely upon to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable legal, regulatory or other requirements;
- our reliance on third parties to produce clinical and commercial supplies of our product candidates;
- our dependence on key personnel and our ability to attract, motivate and retain highly qualified personnel;
- the potential that our use of AI could expose us to liability;
- our ability to obtain and maintain patent and other intellectual property protection for our technology and product candidates;
- the failure to issue (or the threatening of their validity, patentability, enforceability, breadth or strength of protection) or provide meaningful exclusivity for our product candidates of our patent applications that we own or have in-licensed;
- the inadequacy of patent terms and their scope to protect our competitive position;
- 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;
- dilution of ownership caused by future sales and issuances of our or the Vants' equity securities or rights to purchase equity securities;
- future sales, or the perception of future sales, of our common shares by us or our existing shareholders, 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 IA. "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)

	June 30, 2025	March 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 1,238,459	$ 2,715,411
Marketable securities (includes $1,803,035 of available-for-sale marketable securities held at fair value as of June 30, 2025)	3,264,692	2,171,480
Other current assets	112,600	113,173
Total current assets	4,615,751	5,000,064
Property and equipment, net	14,865	12,056
Operating lease right-of-use assets	87,078	89,021
Investments measured at fair value	283,814	302,939
Other assets	31,094	32,860
Total assets	$ 5,032,602	$ 5,436,940
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 11,550	$ 23,691
Accrued expenses	88,728	114,294
Operating lease liabilities	9,402	9,842
Other current liabilities	4,186	1,584
Total current liabilities	113,866	149,411
Liability instruments measured at fair value	12,310	9,981
Operating lease liabilities, noncurrent	90,292	90,328
Other liabilities	228	22
Total liabilities	216,696	249,742
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 682,229,832 and 695,938,323 shares issued and outstanding at June 30, 2025 and March 31, 2025, respectively	—	—
Additional paid-in capital	4,644,085	4,562,107
(Accumulated deficit) / retained earnings	(315,588)	116,060
Accumulated other comprehensive income	17,137	9,438
Shareholders' equity attributable to Roivant Sciences Ltd.	4,345,634	4,687,605
Noncontrolling interests	470,272	499,593
Total shareholders' equity	4,815,906	5,187,198
Total liabilities and shareholders' equity	$ 5,032,602	$ 5,436,940

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 June 30,	
	2025	**2024**
Revenue	$ 2,170	$ 7,990
Operating expenses:		
Cost of revenues	154	213
Research and development (includes $11,099 and $10,532 of share-based compensation expense for the three months ended June 30, 2025 and 2024, respectively)	152,919	120,507
General and administrative (includes $71,079 and $36,841 of share-based compensation expense for the three months ended June 30, 2025 and 2024, respectively)	134,019	99,892
Total operating expenses	287,092	220,612
Gain on sale of Telavant net assets	—	110,387
Loss from operations	(284,922)	(102,235)
Change in fair value of investments	19,125	(15,226)
Change in fair value of liability instruments	2,329	1,150
Interest income	(48,322)	(72,127)
Other expense, net	11,208	3,608
Loss from continuing operations before income taxes	(269,262)	(19,640)
Income tax expense	4,649	11,963
Loss from continuing operations, net of tax	(273,911)	(31,603)
Income from discontinued operations, net of tax	—	89,093
Net (loss) income	(273,911)	57,490
Net loss attributable to noncontrolling interests	(50,556)	(37,807)
Net (loss) income attributable to Roivant Sciences Ltd.	$ (223,355)	$ 95,297
Amounts attributable to Roivant Sciences Ltd.:		
(Loss) income from continuing operations, net of tax	$ (223,355)	$ 6,049
Income from discontinued operations, net of tax	—	89,248
Net (loss) income attributable to Roivant Sciences Ltd.	$ (223,355)	$ 95,297
Net (loss) income per common share, basic:		
(Loss) income from continuing operations, net of tax	$ (0.33)	$ 0.01
Income from discontinued operations, net of tax	$ —	$ 0.12
Net (loss) income per common share	$ (0.33)	$ 0.13
Net (loss) income per common share, diluted:		
(Loss) income from continuing operations, net of tax	$ (0.33)	$ 0.01
Income from discontinued operations, net of tax	$ —	$ 0.11
Net (loss) income per common share	$ (0.33)	$ 0.12
Weighted average shares outstanding:		
Basic	680,286,922	735,816,536
Diluted	680,286,922	781,627,601

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

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

	Three Months Ended June 30,	
	2025	**2024**
Net (loss) income	$ (273,911)	$ 57,490
Other comprehensive income (loss):		
Change in fair value of debt due to change in subsidiary credit risk	—	(10,600)
Unrealized gains on available-for-sale securities	470	—
Foreign currency translation adjustment	7,739	(3,232)
Total other comprehensive income (loss)	8,209	(13,832)
Comprehensive (loss) income	(265,702)	43,658
Comprehensive loss attributable to noncontrolling interests	(50,046)	(37,774)
Comprehensive (loss) income attributable to Roivant Sciences Ltd.	$ (215,656)	$ 81,432

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 Income	Retained Earnings / (Accumulated Deficit)	Noncontrolling Interests	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2025	**695,938,323**	**$ —**	**$ 4,562,107**	**$ 9,438**	**$ 116,060**	**$ 499,593**	**$ 5,187,198**
Issuance of the Company's common shares in connection with equity incentive plans, net of forfeitures, and tax withholding payments	6,560,959	—	16,912	—	—	—	16,912
Exercise and vesting of subsidiary share awards	—	—	2,325	—	—	1,288	3,613
Cash contributions to majority-owned subsidiaries	—	—	(290)	—	—	290	—
Unrealized gains on available-for-sale securities	—	—	—	470	—	—	470
Repurchase of the Company's common shares	(20,269,450)	—	—	—	(208,293)	—	(208,293)
Share-based compensation	—	—	63,031	—	—	19,147	82,178
Foreign currency translation adjustment	—	—	—	7,229	—	510	7,739
Net loss	—	—	—	—	(223,355)	(50,556)	(273,911)
Balance at June 30, 2025	**682,229,832**	**$ —**	**$ 4,644,085**	**$ 17,137**	**$ (315,588)**	**$ 470,272**	**$ 4,815,906**

	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
Exercise and vesting of subsidiary share awards	—	—	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**

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)

	Three Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss (income)	$ (273,911)	$ 57,490
Adjustments to reconcile net loss (income) to net cash used in operating activities:		
Share-based compensation	82,178	50,191
Change in fair value of investments	19,125	(15,226)
Change in fair value of debt and liability instruments	2,329	(118,202)
Gain on sale of Telavant net assets	—	(110,387)
Accretion of discount and amortization of premium on marketable securities, net	(11,061)	—
Depreciation and amortization	1,098	4,883
Non-cash lease expense	1,943	1,581
Other	11,082	5,576
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Other current assets	128	(16,334)
Accounts payable	(11,745)	(25,267)
Accrued expenses	(25,000)	(37,584)
Operating lease liabilities	(478)	(1,816)
Other	(71)	12,266
Net cash used in operating activities	(204,383)	(192,829)
Cash flows from investing activities:		
Purchases of marketable securities	(1,801,681)	—
Maturities of marketable securities	720,000	—
Purchase of property and equipment	(4,035)	(965)
Net cash used in investing activities	(1,085,716)	(965)
Cash flows from financing activities:		
Repayment of debt by subsidiary	—	(1,500)
Payments on principal portion of finance lease obligations	—	(329)
Proceeds from exercise of the Company's and subsidiary stock options	30,057	2,271
Taxes paid related to net settlement of equity awards	(9,532)	(12,673)
Repurchase of common shares	(208,293)	(648,385)
Net cash used in financing activities	(187,768)	(660,616)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	815	(2,740)
Net change in cash, cash equivalents and restricted cash	(1,477,052)	(857,150)
Cash, cash equivalents and restricted cash at beginning of period	2,725,661	6,550,450
Cash, cash equivalents and restricted cash at end of period	$ 1,248,609	$ 5,693,300
Non-cash investing and financing activities:		
Issuance of subsidiary shares in connection with Debt Renegotiation	$ —	$ 11,647
Other	$ 44	$ 113

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'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.

(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 June 30, 2025, the Company had cash, cash equivalents, and marketable securities of approximately $4.5 billion and its accumulated deficit was $315.6 million. For the three months ended June 30, 2025 and 2024, the Company incurred net losses from continuing operations of $273.9 million and $31.6 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.

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, 2025 filed with the SEC. The unaudited condensed consolidated balance sheet at March 31, 2025 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 three months ended June 30, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2026, 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 the Company, solely in its capacity as the representative of the securityholders of Dermavant. Organon's acquisition of Dermavant (the "Dermavant Transaction") was completed in October 2024 and the Company determined the acquisition met the discontinued operations accounting criteria. As the Dermavant Transaction closed in October 2024, no Dermavant assets or liabilities were recognized on the balance sheet as of March 31, 2025 or June 30, 2025. Accordingly, the Company classified the results of Dermavant as discontinued operations in its condensed consolidated statements of operations for the three months ended June 30, 2024. 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 information on the discontinued operations 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.

The Company has long-lived assets in different geographic locations. As of June 30, 2025 and March 31, 2025, a majority of the Company's long-lived assets were located in the United States ("U.S.").

(D) Segment Reporting

Operating segments are defined as components of an entity about which separate, discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker views the operations and manages the business in a single operating and reportable segment focused on the discovery, development and commercialization of medicines and technologies. The accounting policies of the segment are the same as those described in this Note 2, "Summary of Significant Accounting Policies." See Note 15, "Segment Information" for further detail.

(E) Cash, Cash Equivalents, and Restricted Cash

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

	June 30, 2025	March 31, 2025
Cash and cash equivalents	$ 1,238,459	$ 2,715,411
Restricted cash (included in "Other current assets")	2,258	2,358
Restricted cash (included in "Other assets")	7,892	7,892
Cash, cash equivalents and restricted cash	$ 1,248,609	$ 2,725,661

(F) 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. The Company's marketable securities are classified as available-for-sale or held-to-maturity and are carried at fair value or amortized cost, respectively. Unrealized holding gains and losses, net of income taxes, on available-for-sale debt securities are reflected as a separate component of stockholders' equity until realized. The cost of marketable securities sold and the amount reclassified out of accumulated other comprehensive income into earnings is determined using the specific identification method. Interest income is recorded as earned within "Interest income" in the condensed consolidated statements of operations.

(G) 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.

(H) 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."

(I) 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.
- 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") and Class A units of Heracles Parent, L.L.C. ("Datavant"). The Company's financial instruments also include liability instruments issued, including the earn-out shares liabilities issued in connection with the Company's business combination (the "Business Combination") with Montes Archimedes Acquisition Corp. ("MAAC") (as discussed in Note 12, "Earn-Out Shares"); its investments in other entities; cash; cash equivalents, consisting of money market funds; 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. Marketable securities are classified as available-for-sale or held-to-maturity and are carried at fair value or amortized cost, respectively.

(J) Share-Based Compensation

Share-based awards to employees, directors, and consultants include stock options, restricted stock units ("RSUs"), performance options, performance restricted stock units ("PSUs") and capped value appreciation rights ("CVARs").

The Company measures the fair value of its stock options that only have service vesting requirements or performance-based options without market conditions using the Black-Scholes option pricing model. Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company's shares of common stock. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. In prior fiscal years, because the Company did not have sufficient trading history to rely on the volatility of its common stock, volatility was estimated by taking the average historical price volatility for comparable publicly traded peer companies. Beginning on April 1, 2025, the Company began using a blend of its historical and implied volatility to estimate the expected share price volatility assumption. Due to changes in the Company's capital position, the Company believes this methodology better reflects its expected future volatility. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The Company accounts for pre-vesting award forfeitures when they occur. As RSL's common shares are publicly traded, the Company determines the fair value of each common share underlying share-based awards based on the closing price of its common shares as reported by Nasdaq on the date of grant. For privately held Vants, the fair value of the shares of common stock underlying share-based awards on each grant date is estimated, given the absence of a public trading market.

(K) Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. For the Company's subsidiaries whose functional currency is other than the U.S. dollar, assets and liabilities are translated into U.S. dollars at the exchange rates in effect at the balance sheet date, while their revenue and expenses are translated at the average exchange rates for the reporting period. The cumulative foreign currency translation adjustments are recorded as a component of "Accumulated other comprehensive income (loss)" in the accompanying condensed consolidated statement of shareholders' equity.

Transaction gains and losses that arise from exchange rate fluctuations on transactions denominated in a currency other than the functional currency are included in "Other expense, net" in the accompanying condensed consolidated statements of operations. For the three months ended June 30, 2025, foreign currency transaction losses were $6.8 million. Foreign currency transaction losses were immaterial for the three months ended June 30, 2024.

(L) 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, 2025.

(M) Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued 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 Company adopted the guidance in the Company's Form 10-K for the year ended March 31, 2025 and has made the required disclosures in this Form 10-Q.

(N) 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 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.

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure of certain costs and expenses on an interim and annual basis in the notes to the financial statements. The amendments are effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2028, and subsequent interim periods, with early adoption permitted. The amendments can be adopted either (i) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (ii) retrospectively to any or all prior periods presented in the financial statements. 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):

	June 30, 2025	March 31, 2025
Cash and cash equivalents		
Cash	$ 94,787	$ 93,954
Money market funds	1,143,672	2,621,457
Total cash and cash equivalents	$ 1,238,459	$ 2,715,411
Marketable securities		
U.S. Treasury securities, available-for-sale	$ 1,803,035	$ —
U.S. Treasury securities, held-to-maturity	1,461,657	2,171,480
Total marketable securities	$ 3,264,692	$ 2,171,480
Total cash, cash equivalents, and marketable securities	$ 4,503,151	$ 4,886,891

The following table summarizes the unrealized positions for the Company's marketable securities (in thousands):

	As of June 30, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities, available-for-sale	$ 1,802,565	$ 654	$ (184)	$ 1,803,035
U.S. Treasury securities, held-to-maturity	1,461,657	211	(603)	1,461,265
Total marketable securities	$ 3,264,222	$ 865	$ (787)	$ 3,264,300

The Company classified its marketable securities as Level 2 measurements within the fair value hierarchy. As of June 30, 2025, 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 June 30, 2025 and March 31, 2025, 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 June 30, 2025, RSL held approximately 20% of the issued and outstanding shares of Arbutus.

At June 30, 2025 and March 31, 2025, the aggregate fair value of the Company's investment in Arbutus was $120.0 million and $135.6 million, respectively with the Company recognizing an unrealized loss of $15.5 million and unrealized gain of $19.8 million on its investment in Arbutus in the accompanying condensed consolidated statements of operations for the three months ended June 30, 2025 and 2024, respectively. The fair value of the Company's investment was determined using the closing price of Arbutus's common stock on June 30, 2025 and March 31, 2025 of $3.09 and $3.49, respectively.

Investment in Datavant

The Company holds an investment in Class A units of Datavant. As of June 30, 2025, 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 June 30, 2025 and March 31, 2025, the fair value of the Company's investment was $163.8 million and $167.4 million, respectively with the Company recognizing unrealized losses of $3.6 million and $4.6 million on its investment in Datavant in the accompanying condensed consolidated statements of operations for the three months ended June 30, 2025 and 2024, respectively.

The fair value of the Company's investment was determined using valuation models that incorporate significant unobservable inputs and is classified as a Level 3 measurement within the fair value hierarchy. Refer to Note 13, "Fair Value Measurements" for more information.

Note 5—Recent Transactions and Developments

Telavant Disposition

On December 14, 2023, 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"). 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. Refer to Note 5, "Recent Transactions and Developments" in the Company's Annual Report on Form 10-K for the year ended March 31, 2025 for further information regarding the Roche Transaction.

Pursuant to the Stock Purchase Agreement, the Company was due its pro rata portion of a one-time milestone payment of $150 million, following the initiation of a Phase 3 trial in ulcerative colitis. In June 2024, the one-time milestone was achieved. The milestone payment was paid to all of Telavant's equity holders, including holders of Telavant RSUs, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction. Accordingly, the Company recognized a gain on sale of Telavant net assets of $110.4 million for its pro rata portion during the three months ended June 30, 2024 in the accompanying condensed consolidated statements of operations.

Note 6—Discontinued Operations

On October 28, 2024, the Company completed the sale of its entire equity interest in its majority-owned subsidiary, Dermavant, to Organon. The Dermavant Transaction was made pursuant to the Merger Agreement between Dermavant, Organon, Merger Sub, and the Company. Pursuant to the Merger Agreement, Organon agreed to acquire Dermavant for cash consideration comprising an upfront payment, regulatory and sales milestones, and royalties. Refer to Note 6, "Discontinued Operations" in the Company's Annual Report on Form 10-K for the year ended March 31, 2025 for further information regarding the Dermavant Transaction.

The Company concluded that Dermavant met the discontinued operations accounting criteria in the second fiscal quarter of 2024. As the Dermavant Transaction closed in October 2024, no Dermavant assets or liabilities were recognized on the balance sheet as of March 31, 2025 or June 30, 2025. Financial results of Dermavant are presented as "Income from discontinued operations, net of tax" in the accompanying condensed consolidated statements of operations for the three months ended June 30, 2024.

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

	June 30, 2024
Product revenue, net	$ 18,367
License, milestone and other revenue	28,775
Revenue, net	47,142
Operating expenses:	
Cost of revenues	3,765
Research and development	12,701
Selling, general and administrative	48,626
Total operating expenses	65,092
Loss from operations	(17,950)
Change in fair value of debt	(119,352)
Interest expense[1]	13,399
Other income, net	(1,782)
Income from discontinued operations before income taxes	89,785
Income tax expense	692
Income from discontinued operations, net of tax	$ 89,093
Loss from discontinued operations before income taxes attributable to noncontrolling interests	$ (155)
Income from discontinued operations before income taxes attributable to Roivant Sciences Ltd.	89,940
Income from discontinued operations before income taxes	$ 89,785

[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.

In the accompanying condensed 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 for the three months ended June 30, 2024 (in thousands):

	June 30, 2024
Share-based compensation	$ 2,780
Change in fair value of debt	$ (119,352)
Depreciation and amortization	$ 2,834

Note 7—Certain Balance Sheet Components

Accrued Expenses

Accrued expenses at June 30, 2025 and March 31, 2025 consisted of the following (in thousands):

	June 30, 2025	March 31, 2025
Research and development expenses	$ 49,801	$ 45,813
Compensation-related expenses	26,534	53,928
Other expenses	12,393	14,553
Total accrued expenses	$ 88,728	$ 114,294

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 June 30, 2025, 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). This repurchase program was funded by available cash and cash equivalents on hand. 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. Subsequent to the repurchase of the common shares held by Sumitomo, additional repurchases of 57,110,703 shares were made in open market transactions under the share repurchase program during the year ended March 31, 2025 for an aggregate purchase price of approximately $644.8 million. During the three months ended June 30, 2025, repurchases of 20,269,450 shares were made for an aggregate purchase price of approximately $208.3 million. The $1.5 billion common share repurchase program was completed as of June 30, 2025.

On June 24, 2025, in addition to the $1.5 billion common share repurchase program, the Company's board of directors authorized a common share repurchase program allowing for repurchases of the Company's common shares in an aggregate amount of up to $500 million (excluding fees and expenses). No purchases have been made as of June 30, 2025.

Note 9—Share-Based Compensation and Other Compensation Plans

(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 June 30, 2025, a total of 37,219,786 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 three months ended June 30, 2025 was as follows:

	Number of Options
Options outstanding at March 31, 2025	139,412,098
Granted	1,976,147
Exercised	(5,481,656)
Forfeited/Canceled	(313,373)
Options outstanding at June 30, 2025	135,593,216
Options exercisable at June 30, 2025	113,027,137

Restricted Stock Units

Activity for RSUs under the RSL Equity Plans for the three months ended June 30, 2025 was as follows:

	Number of RSUs
Non-vested balance at March 31, 2025	14,119,949
Granted	4,097,713
Vested	(1,605,772)
Forfeited	(373,237)
Non-vested balance at June 30, 2025	16,238,653

Performance Restricted Stock Units

As of June 30, 2025, 36,872,465 PSUs granted under the RSL Equity Plans remain unvested. During the three months ended June 30, 2025, no PSUs were granted or forfeited.

Capped Value Appreciation Rights

March 2020 CVAR Grants

As of June 30, 2025, 17,548,368 CVARs granted in March 2020 remain outstanding. These CVARs had met the service vesting condition as of June 30, 2025 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 annually on 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 three months ended June 30, 2025 was as follows:

	Number of CVARs
Non-vested balance at March 31, 2025	348,527
Vested	(297,795)
Forfeited	(50,732)
Non-vested balance at June 30, 2025	—

During the three months ended June 30, 2025, 297,795 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 $19.3 million and $14.7 million for the three months ended June 30, 2025 and 2024, respectively, related to subsidiary EIPs.

(C) 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 June 30, 2025, the Company recognized general and administrative expense and research and development expense of $2.1 million and $0.5 million, respectively, relating to the Cash Bonus Program. During the three months ended June 30, 2024, the Company recognized general and administrative expense and research and development expense of $6.9 million and $1.8 million, respectively, relating to the Cash Bonus Program.

(D) 2024 Senior Executive Compensation Program Cash Awards

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 Immunovant CEO (the “2024 Senior Executive 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 Immunovant CEO	$ 7,465

Mr. Gline and Dr. Venker received 75% of their respective cash retention awards as of June 30, 2025. 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 March 31, 2025. If a Recoupment Event (as defined below) occurs on or prior to September 30, 2025, 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 June 30, 2025.

As a result of the cash retention rewards, the Company recognized general and administrative expense of $3.7 million during the three months ended June 30, 2025. The remaining portion of $3.6 million as of June 30, 2025 will be recognized over the remaining service period ending September 30, 2025.

Note 10—Income Taxes

The Company's effective tax rate for the three months ended June 30, 2025 and 2024 was (1.7)% and (60.9)%, respectively. The effective tax rate for the three months ended June 30, 2025 is driven by the Company's earnings by jurisdiction and a valuation allowance that eliminates the Company's global net deferred tax assets. The effective tax rate for the three months ended June 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 the earnings by jurisdiction 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.

On July 4, 2025, H.R. 1, 119th Cong. (2025), also referred to as the "One Big Beautiful Bill Act" (the "2025 Tax Act" or "OBBBA") was signed into law in the U.S, which includes a broad range of tax reform provisions. ASC740, "Income Tax", requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the legislation is enacted. The Company is currently evaluating the impact of the OBBBA on its consolidated financial statements.

Note 11—Commitments and Contingencies

(A) Commitments

Lease Commitments

The Company has leases, consisting primarily of real estate leases. Refer to Note 11, "Leases" in the Company's Annual Report on Form 10-K for the year ended March 31, 2025 for further information regarding the Company's lease commitments.

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 12, "Commitments and Contingencies" in the Company's Annual Report on Form 10-K for the year ended March 31, 2025 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 three months ended June 30, 2025. The Company has further commitments relating to other asset acquisition and license agreements that it has entered into 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 June 30, 2025, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $43.1 million.

(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 June 30, 2025 and March 31, 2025.

Note 12—Earn-Out Shares

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

a. 2,033,591 common shares to Patient Square Capital LLC (the "MAAC Sponsor") and 10,000 common shares issued to each of MAAC's independent directors (collectively, the "20% Earn-Out Shares"), which will vest if the closing price of the Company's common shares is greater than or equal to $15.00 over any 20 out of 30 trading day period during the Vesting Period (defined below).

b. 1,016,796 common shares issued to the MAAC Sponsor and 5,000 common shares issued to each of MAAC's independent directors (collectively, the "10% Earn-Out Shares" and, together with the 20% Earn-Out Shares, the "Earn-Out Shares"), each in respect of its MAAC Class B Shares, will vest if the closing price of the Company's common shares is greater than or equal to $20.00 over any 20 out of 30 trading day period during the Vesting Period (as defined below).

c. The remaining number of common shares issued to the MAAC Sponsor and each of MAAC's independent directors are not subject to the vesting conditions described above.

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

The Earn-Out Shares require liability classification and are classified as "Liability instruments measured at fair value" on the 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 June 30, 2025, 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 June 30, 2025 and March 31, 2025, by level, within the fair value hierarchy (in thousands):

	As of June 30, 2025				As of March 31, 2025			
	Level 1	Level 2	Level 3	Balance as of June 30, 2025	Level 1	Level 2	Level 3	Balance as of March 31, 2025
Assets:								
Money market funds	$ 1,143,672	$ —	$ —	$ 1,143,672	$ 2,621,457	$ —	$ —	$ 2,621,457
Available-for-sale marketable securities	—	1,803,035	—	1,803,035	—	—	—	—
Investment in Datavant Class A units	—	—	163,775	163,775	—	—	167,361	167,361
Investment in Arbutus common shares	120,039	—	—	120,039	135,578	—	—	135,578
Total assets at fair value	$ 1,263,711	$ 1,803,035	$ 163,775	$ 3,230,521	$ 2,757,035	$ —	$ 167,361	$ 2,924,396
Liabilities:								
Liability instruments measured at fair value[1]	—	—	12,310	12,310	—	—	9,981	9,981
Total liabilities at fair value	$ —	$ —	$ 12,310	$ 12,310	$ —	$ —	$ 9,981	$ 9,981

[1] At June 30, 2025, Level 3 includes the fair value of the Earn-Out Shares of $12.3 million. At March 31, 2025, Level 3 includes the fair value of the Earn-Out Shares of $10.0 million.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the three months ended June 30, 2025.

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 three months ended June 30, 2025 and 2024 were as follows (in thousands):

Balance at March 31, 2024	$ 147,526
Changes in fair value of investment in Datavant, included in net income	(4,586)
Balance at June 30, 2024	$ 142,940
Balance at March 31, 2025	$ 167,361
Changes in fair value of investment in Datavant, included in net loss	(3,586)
Balance at June 30, 2025	$ 163,775

The changes in fair value of the Level 3 liabilities during the three months ended June 30, 2025 and 2024 were as follows (in thousands):

Balance at March 31, 2024	$ 25,737
Changes in fair value of liability instruments, included in net income	1,150
Balance at June 30, 2024	$ 26,887
Balance at March 31, 2025	$ 9,981
Changes in fair value of liability instruments, included in net loss	2,329
Balance at June 30, 2025	$ 12,310

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 June 30, 2025**	**As of March 31, 2025**
Volatility	100.0%	110.0%
Discount rate	13.0%	13.0%

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 June 30, 2025**	**As of March 31, 2025**
Volatility	36.5%	38.4%
Risk-free rate	3.90%	3.96%

As of March 31, 2025, the Company began using a blend of its historical and implied volatility, rather than exclusively relying on historical volatility, to estimate the expected volatility assumption of various equity instruments issued by the Company. Due to changes in the Company's capital position, the Company believes this methodology better reflects its expected future volatility.

As of June 30, 2025 and March 31, 2025, the fair value of the Earn-Out Shares was $12.3 million and $10.0 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. For the three months ended June 30, 2025 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 June 30, 2025 and 2024, the following potentially dilutive common stock equivalents were excluded from the computation of diluted net (loss) income per common share:

	June 30, 2025	**June 30, 2024**
Stock options and performance stock options	135,593,216	54,648,258
Restricted stock units and performance stock units (non-vested)	53,111,118	5,422,465
March 2020 CVARs[(1)]	17,548,368	17,548,368
November 2021 CVARs (non-vested)	—	200,722
Restricted common stock (non-vested)	—	255,911
Earn-Out Shares (non-vested)	3,080,387	3,080,387
Other stock based awards and instruments issued	4,485,265	3,924,305

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

Note 15—Segment Information

The Company is operated and managed as a single operating and reportable segment which focuses on the discovery, development and commercialization of medicines and technologies. The Company's Chief Operating Decision Maker ("CODM") is its chief executive officer.

The CODM assesses performance for the Company based on net (loss) income, which is reported on the condensed consolidated statements of operations and comprehensive (loss) income as net (loss) income. The measure of segment assets is reported on the condensed consolidated balance sheets as total assets.

The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. As such, the CODM uses cash forecast models and budgeted versus actual results to assess performance, make operating decisions and allocate resources across the Company including to various Vants and research and development projects.

The Company's significant segment expenses are as follows *(in thousands)*:

	Three Months Ended June 30,	
	2025	2024
Revenue	$ 2,170	$ 7,990
Less:		
Cost of revenues	154	213
Program-specific research and development expenses:		
Anti-FcRn franchise—neurological diseases	20,937	18,479
Anti-FcRn franchise—endocrine diseases	19,329	15,913
Anti-FcRn franchise—rheumatology diseases	8,209	—
Anti-FcRn franchise—dermatology diseases	5,145	—
Anti-FcRn franchise—other clinical and nonclinical	2,392	6,401
Brepocitinib	15,020	10,594
Mosliciguat	8,385	2,980
Other development and discovery programs	10,236	15,515
Research and development share-based compensation	11,099	10,532
Research and development personnel-related expenses	42,530	31,545
Other research and development expenses	9,637	8,548
General and administrative share-based compensation	71,079	36,841
General and administrative personnel-related expenses	30,110	29,697
Other general and administrative expenses	32,830	33,354
Gain on sale of Telavant net assets	—	(110,387)
Change in fair value of investments	19,125	(15,226)
Change in fair value of liability instruments	2,329	1,150
Interest income	(48,322)	(72,127)
Other expense, net	11,208	3,608
Income tax expense	4,649	11,963
Income from discontinued operations, net of tax	—	(89,093)
Net (loss) income	$ (273,911)	$ 57,490

Note 16—Subsequent Events

In July 2025, the board of directors appointed Frank Torti as an executive officer of the Company and as President and Vant Chair at the Company's wholly-owned subsidiary, Roivant Sciences, Inc. ("RSI"). In connection with this appointment, the Compensation Committee approved a compensation package for Dr. Torti consisting of (i) a one-time cash retention award, (ii) PSUs with both performance- and time-vesting components and (iii) time-vesting RSUs. The Company is evaluating the accounting impact of these awards and will include relevant disclosures in its Form 10-Q for the three months ending September 30, 2025.

A summary of the awards approved is as follows:

Executive	Title	Performance Restricted Stock Units (at max) (#)	Restricted Stock Units (#)	Cash Awards ($ in thousands)
Frank Torti	RSI President and Vant Chair	11,900,000	1,836,547	$ 7,500

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, 2025, included in our Annual Report on Form 10-K, filed with the SEC on May 29, 2025 (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 "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 brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 in development for the treatment of dermatomyositis, non-infectious uveitis and cutaneous sarcoidosis; IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting FcRn in development across several IgG-mediated autoimmune indications; and mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease. 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
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Non-Infectious Uveitis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Cutaneous Sarcoidosis	Priovant	Small Molecule	Phase 2
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	Sjögren's Disease	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Cutaneous Lupus Erythematosus	Immunovant	Biologic	Phase 2
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 3*
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.*

Vant Ownership

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of June 30, 2025, as well as our ownership interest in potential future milestones and royalties related to the Dermavant Transaction (see footnote 4 below).

	Roivant Ownership	
Vant / Milestones & Royalties	Basic[1]	Fully Diluted[2]
Priovant	74%	65%
Immunovant	57%[3]	51%[3]
Pulmovant	99%	92%
Genevant	83%	64%
Covant	97%	90%
Psivant	36%	33%
Arbutus	20%[3]	19%[3]
Lokavant	57%	51%
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, 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. In January 2025, we received 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) 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 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 condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.*

† *As of June 30, 2025, 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.*

Upcoming Catalysts

In the upcoming year, we have a robust set of expected near-term catalysts, including the items set forth in the table 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
LNP platform	Genevant	Summary judgement phase in U.S. Moderna case	Ongoing
Batoclimab	Immunovant	Additional data in Graves' disease including 6-month remission data	September 2025
Brepocitinib	Priovant	Topline data from Phase 3 trial in dermatomyositis	2H 2025
Batoclimab	Immunovant	Topline data from Phase 3 trials in thyroid eye disease	2H 2025
LNP platform	Genevant	Markman hearing decision in Pfizer/BioNTech case	2025*
LNP platform	Genevant	Jury trial in U.S. Moderna case	1Q 2026
Mosliciguat	Pulmovant	Topline data from Phase 2 trial in pulmonary hypertension associated with interstitial lung disease	2H 2026
Brepocitinib	Priovant	Topline data from Phase 2 trial in cutaneous sarcoidosis	2H 2026
IMVT-1402	Immunovant	Initial results from open label period 1 of potentially registrational trial in ACPA+ difficult-to-treat rheumatoid arthritis	2026
IMVT-1402	Immunovant	Topline data from Phase 2 trial in cutaneous lupus erythematosus	2026
Brepocitinib	Priovant	Topline data from Phase 3 trials in non-infectious uveitis	1H 2027
IMVT-1402	Immunovant	Topline data from potentially registrational trial in ACPA+ difficult-to-treat rheumatoid arthritis	2027
IMVT-1402	Immunovant	Topline data from potentially registrational trials in Graves' disease	2027
IMVT-1402	Immunovant	Topline data from potentially registrational trial in myasthenia gravis	2027
IMVT-1402	Immunovant	Topline data from potentially registrational trial in Sjögren's disease	2028
IMVT-1402	Immunovant	Topline data from potentially registrational trial in chronic inflammatory demyelinating polyneuropathy	2028

Note: References under "Expected Timing" are to calendar years. All catalyst timings are based on current expectations and, where applicable, contingent on FDA feedback, and may be subject to change. The timing of the litigation-related events noted above is subject to change, including at the discretion of the court.

** The court in the Pfizer/BioNTech case has not provided guidance for the timing of its ruling for the Markman hearing, which could potentially be in 2025.*

Recent Developments

- **Priovant:** Phase 3 VALOR study for brepocitinib evaluating its use in patients with DM remains on track for topline data readout in the second half of calendar year 2025, with last patient last visit completed in July. Roivant and Priovant hosted an investor event on brepocitinib in June and shared details about the ongoing VALOR DM study, including pooled/blinded baseline data, clinical endpoints details and successful steroid tapering data. Phase 3 trial for brepocitinib in non-infectious uveitis (NIU) is actively enrolling and on track for topline readout in the first half of calendar year 2027. Proof-of-concept trial for brepocitinib in cutaneous sarcoidosis (CS) is actively enrolling and on track for topline readout in the second half of calendar year 2026.

- **Immunovant:** In June 2025, Immunovant initiated a second potentially registrational trial evaluating IMVT-1402 in GD and a potentially registrational trial evaluating IMVT-1402 in SjD. All clinical development timelines remain on track for IMVT-1402 across six announced indications, including potentially registrational trials in Graves' disease (GD), difficult-to-treat rheumatoid arthritis (D2T RA), myasthenia gravis (MG), chronic inflammatory demyelinating polyneuropathy (CIDP) and Sjögren's disease (SjD), and a proof-of-concept trial in cutaneous lupus erythematosus (CLE).

- **Roivant:** Roivant reported consolidated cash, cash equivalents, restricted cash and marketable securities of $4.5 billion at June 30, 2025, supporting cash runway into profitability. Roivant completed its $1.5 billion share repurchase program, including $208 million in repurchases this quarter, reducing outstanding shares by over 15% from March 31, 2024. A new $500 million share repurchase program was approved by the board of directors in June 2025.

Components of Results of Operations

Revenue

Revenue primarily relates to amounts earned 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 research and development related 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 in-licensed assets through preclinical studies and clinical trials, as well as acquire or discover new product candidates.

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; and
- our ability to maintain a continued acceptable safety profile of our product candidates following regulatory 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 potential commercialization efforts. These increases will likely include additional costs related to the hiring of new personnel 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 Immunovant CEO (the “2024 Senior Executive Compensation Program”). The long-term equity incentive awards granted pursuant to this program will result in significant share-based compensation expense over the vesting period of the awards. Refer to Note 9, “Share-Based Compensation and Other Compensation Plans” of our financial statements for further details.

Gain on sale of Telavant net assets

Gain on sale of Telavant net assets reflects a gain resulting from the achievement of a one-time milestone in June 2024 at Telavant Holdings, Inc. ("Telavant") for our pro rata portion of the consideration. Refer to Note 5, "Recent Transactions and Developments" for further information.

Change in fair value of investments

Change in fair value of investments includes the unrealized losses 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.

Interest income

Interest income consists of interest earned on our 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.

Income from discontinued operations, net of tax

Income from discontinued operations, net of tax consists of the financial results of Dermavant Sciences Ltd. ("Dermavant") during the three months ended June 30, 2024. 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 months ended June 30, 2025 and 2024

The following table sets forth our results of operations for the three months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Revenue	$ 2,170	$ 7,990	$ (5,820)
Operating expenses:			
Cost of revenues	154	213	(59)
Research and development	152,919	120,507	32,412
General and administrative	134,019	99,892	34,127
Total operating expenses	287,092	220,612	66,480
Gain on sale of Telavant net assets	—	110,387	(110,387)
Loss from operations	(284,922)	(102,235)	(182,687)
Change in fair value of investments	19,125	(15,226)	34,351
Change in fair value of liability instruments	2,329	1,150	1,179
Interest income	(48,322)	(72,127)	23,805
Other expense, net	11,208	3,608	7,600
Loss from continuing operations before income taxes	(269,262)	(19,640)	(249,622)
Income tax expense	4,649	11,963	(7,314)
Loss from continuing operations, net of tax	(273,911)	(31,603)	(242,308)
Income from discontinued operations, net of tax	—	89,093	(89,093)
Net (loss) income	(273,911)	57,490	(331,401)
Net loss attributable to noncontrolling interests	(50,556)	(37,807)	(12,749)
Net (loss) income attributable to Roivant Sciences Ltd.	$ (223,355)	$ 95,297	$ (318,652)

Variance analysis for three months ended June 30, 2025 and 2024

Revenue

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Revenue	$ 2,170	$ 7,990	$ (5,820)

Revenue decreased by $5.8 million to $2.2 million for the three months ended June 30, 2025, compared to $8.0 million for the three months ended June 30, 2024. During both the three months ended June 30, 2025 and 2024, revenue was primarily driven by amounts earned in connection with license agreements at Genevant.

Research and development expenses

For the three months ended June 30, 2025 and 2024**,** our research and development expenses consisted of the following:

	Three Months Ended June 30,		
	2025	2024[1]	Change
		(in thousands)	
Program-specific costs:			
Anti-FcRn franchise—neurological diseases	$ 20,937	$ 18,479	$ 2,458
Anti-FcRn franchise—endocrine diseases	19,329	15,913	3,416
Anti-FcRn franchise—rheumatology diseases	8,209	—	8,209
Anti-FcRn franchise—dermatology diseases	5,145	—	5,145
Anti-FcRn franchise—other clinical and nonclinical	2,392	6,401	(4,009)
Brepocitinib	15,020	10,594	4,426
Mosliciguat	8,385	2,980	5,405
Other development and discovery programs [2]	10,236	15,515	(5,279)
Total program-specific costs	89,653	69,882	19,771
Unallocated internal costs:			
Share-based compensation	11,099	10,532	567
Personnel-related expenses	42,530	31,545	10,985
Other expenses	9,637	8,548	1,089
Total research and development expenses	$ 152,919	$ 120,507	$ 32,412

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

[2] For the three months ended June 30, 2025, terminated program expenses consisted of $1.0 million for Namilumab. For the three months ended June 30, 2024, terminated program expenses consisted of $4.4 million for Namilumab and $1.7 million for RVT-2001.

Research and development expenses increased by $32.4 million to $152.9 million for the three months ended June 30, 2025, compared to $120.5 million for the three months ended June 30, 2024. This increase was primarily driven by increases in program-specific costs of $19.8 million and personnel-related expenses of $11.0 million.

The increase of $19.8 million in program-specific costs was primarily driven by increases of $15.2 million related to the anti-FcRn franchise, reflecting the progression of our programs, $5.4 million related to mosliciguat, and $4.4 million related to brepocitinib.

The majority of unallocated share-based compensation and personnel-related expenses were related to the anti-FcRn franchise activities at Immunovant. The increase of $11.0 million in personnel-related expenses was primarily driven by higher headcount to support additional clinical studies for the anti-FcRn franchise.

General and administrative expenses

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
General and administrative	$ 134,019	$ 99,892	$ 34,127

General and administrative expenses increased by $34.1 million to $134.0 million for the three months ended June 30, 2025, compared to $99.9 million for the three months ended June 30, 2024. This increase was due to an increase in share-based compensation expense of $34.2 million, largely as a result of long-term equity incentive awards from the 2024 Senior Executive Compensation Program. Refer to Note 9, “Share-Based Compensation and Other Compensation Plans” in the Company’s Annual Report on Form 10-K for the year ended March 31, 2025 for further information.

A summary of general and administrative expense relating to the special one-time cash retention bonus award to its employees awarded during the year ended March 31, 2024 (the "Cash Bonus Program") and 2024 Senior Executive Compensation Program is as follows:

	Three Months Ended June 30,		Remaining Expense as of June 30, 2025
	2025	2024	
		(in thousands)	
Cash Bonus Program	$ 2,111	$ 6,924	$ 2,399
2024 Senior Executive Compensation Program:			
Cash awards	3,660	—	3,659
Performance restricted stock units	30,157	—	165,866
Restricted stock units	2,307	—	43,073
Stock options	174	—	2,119
Total	$ 38,409	$ 6,924	$ 217,116

Gain on sale of Telavant net assets

	Three Months Ended June 30,		
	2025	2024	Change
		(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 three months ended June 30, 2024 and resulted from the achievement of a one-time milestone in June 2024. Refer to Note 5, "Recent Transactions and Developments" of our financial statements for further information.

Change in fair value of investments

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Change in fair value of investments	$ 19,125	$ (15,226)	$ 34,351

Change in fair value of investments was an unrealized loss of $19.1 million and an unrealized gain $15.2 million for the three months ended June 30, 2025 and 2024, respectively. The change of $34.4 million was primarily driven by changes in the public share prices of our equity investments, including Arbutus, as well as the change in the fair value of our investment in Datavant.

Interest income

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Interest income	$ (48,322)	$ (72,127)	$ 23,805

Interest income decreased by $23.8 million to $48.3 million for the three months ended June 30, 2025, compared to $72.1 million for the three months ended June 30, 2024. The decrease is primarily due to lower cash equivalents and marketable securities balances in our interest-bearing accounts and lower interest rates.

Income tax expense

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Income tax expense	$ 4,649	$ 11,963	$ (7,314)

Income tax expense decreased by $7.3 million to $4.6 million for the three months ended June 30, 2025, compared to $12.0 million for the three months ended June 30, 2024. The decrease is primarily due to our fluctuating earnings by legal entity in various jurisdictions over the periods.

Income from discontinued operations, net of tax

	Three Months Ended June 30,		
	2025	2024	Change
		(in thousands)	
Income from discontinued operations, net of tax	$ —	$ 89,093	$ (89,093)

Income from discontinued operations, net of tax was $89.1 million for the three months ended June 30, 2024 and represents the financial results of Dermavant during this period. Refer to Note 6, “Discontinued Operations” of our financial statements for further information.

Liquidity and Capital Resources

For the three months ended June 30, 2025 and 2024, we incurred net losses from continuing operations of $273.9 million and $31.6 million, respectively. As of June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $4.5 billion and our accumulated deficit was $315.6 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditures for the foreseeable future. However, projections of future cash flows and operating expenses are inherently uncertain and subject to changes, as described under “Risk Factors” in Part II, Item 1A. of this Quarterly Report on Form 10-Q. As a result, our existing cash, cash equivalents and marketable securities may not be sufficient to fund our operating expenses as anticipated, and we may need to raise additional capital to fund our operations.

Our short-term and long-term liquidity requirements as of June 30, 2025 included:

- obligations under our leases (refer to Note 11, “Leases” in our Annual Report on Form 10-K for the year ended March 31, 2025 for further information regarding our lease commitments); and

- certain commitments to Samsung Biologics Co., Ltd. (“Samsung”) pursuant to a Product Service Agreement (“PSA”) entered into 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 additional batches of batoclimab in the four-year period of 2026 through 2029. As of June 30, 2025, the remaining minimum purchase commitment related to this agreement was estimated to be approximately $43.1 million.

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

Additionally, we have certain payment obligations under various asset acquisition and license agreements. Under these agreements we are required to make milestone payments upon successful completion and achievement of certain development, regulatory and commercial milestones. The payment obligations under the asset acquisition and license agreements are contingent upon future events, such as the achievement of specified development, regulatory and commercial milestones, and the amount, timing and likelihood of such payments are not known. We will also be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements. 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.

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). This repurchase program was funded by available cash and cash equivalents on hand. 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. Subsequent to the repurchase of the common shares held by Sumitomo, additional repurchases of 57,110,703 shares were made in open market transactions under the share repurchase program during the fiscal year ended March 31, 2025 for an aggregate purchase price of approximately $644.8 million. During the three months ended June 30, 2025, repurchase of 20,269,450 shares were made for an aggregate purchase price of approximately $208.3 million. This $1.5 billion common share repurchase program was completed as of June 30, 2025.

On June 24, 2025, in addition to the $1.5 billion common share repurchase program, the Company's board of directors authorized a common share repurchase program allowing for repurchases of the Company's common shares in an aggregate amount of up to $500 million (excluding fees and expenses). No purchases have been made as of June 30, 2025.

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 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 product candidates or 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.

While we do not have a need for additional capital to continue our operations as a result of our current liquidity position, we may in the future require additional capital to fund our operations, pursue business opportunities or strategic transactions or respond to challenges, competition or unforeseen circumstances. In that case, 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 or strategic alliances or through 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, if needed, or to pursue business opportunities, including potential acquisitions.

While we do not have a near-term need for additional capital as a result of our current liquidity position, we may in the future require additional capital, and if adequate funds are not available to us, in that case, we may be required to forego potential in-licensing or acquisition opportunities, delay, limit or terminate one or more development or discovery programs, 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 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 acquisitions, divestitures and other strategic transactions." for more information.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended June 30, 2025 and 2024:

	Three Months Ended June 30,	
	2025	**2024**
	(in thousands)	
Net cash used in operating activities	$ (204,383)	$ (192,829)
Net cash used in investing activities	$ (1,085,716)	$ (965)
Net cash used in financing activities	$ (187,768)	$ (660,616)

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 three months ended June 30, 2025, cash used in operating activities increased by $11.6 million to $204.4 million compared to $192.8 million for the three months ended June 30, 2024, largely reflecting greater cash requirements to advance our research and development programs during the three months ended June 30, 2025.

Investing Activities

For the three months ended June 30, 2025 and 2024, cash used in investing activities increased by $1,084.8 million to $1,085.7 million for the three months ended June 30, 2025 from $1.0 million for the three months ended June 30, 2024, primarily related to purchases of marketable securities, partially offset by maturities during the three months ended June 30, 2025.

Financing Activities

For the three months ended June 30, 2025 and 2024, cash used in financing activities decreased by $472.8 million to $187.8 million for the three months ended June 30, 2025 from $660.6 million for the three months ended June 30, 2024, primarily related to a decrease of $440.1 million in the repurchase of our common shares.

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, 2025 in our Form 10-K.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued 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 Company adopted the guidance in the Company's Form 10-K for the fiscal year ended March 31, 2025 and has made the required disclosures in Note 15, "Segment Information" in our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report for disclosure of the information required under ASU 2023-07.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate and foreign currency sensitivities and equity price risk.

Interest Rate Sensitivity

As of June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $4.5 billion. Our management team has broad discretion in respect of use of our cash, cash equivalents and marketable securities. The primary objective of our investment activities is to preserve capital to fund our operations. 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 also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of our account portfolio, a hypothetical 10% change in interest rates would not have a material effect on our financial condition or unaudited condensed consolidated financial statements.

Foreign Currency Sensitivity

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. A hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our financial condition or unaudited condensed consolidated financial statements.

Equity Price Risk

As of June 30, 2025, 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 10% increase or decrease in the fair value of our investments in Arbutus and Datavant would have increased or decreased their fair value as of June 30, 2025 by approximately $28.4 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 June 30, 2025, 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 June 30, 2025 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 June 30, 2025 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 prospects.

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, managing and operating our subsidiaries, which we refer to as "Vants," financing activities, efforts to discover new product candidates and the creation or acquisition of healthcare technology companies and products. 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. Drug development is an inherently uncertain undertaking that involves significant upfront investments and a substantial degree of risk. If we do not successfully address and manage these risks, our business and prospects will suffer.

Our ability to execute on our business model, successfully develop and commercialize product candidates and eventually generate revenues from the sales of our product candidates following regulatory approvals depends on a number of factors, including our ability to:

- successfully progress and complete our ongoing and future clinical trials;
- identify and consummate new acquisition or in-licensing opportunities, and then advance the acquired or in-licensed product candidates through clinical trials;
- obtain regulatory approvals for our current and future product candidates;
- successfully launch commercial sales of our product candidates following regulatory approvals, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- set acceptable prices for our product candidates following regulatory approvals and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of our product candidates following regulatory approvals in the medical community and with third-party payors and consumers;
- make milestone, royalty or other payments due under any licenses or agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;

- realize the benefits of our strategic partnerships and other collaborations, including the Dermavant Transaction;
- attract, hire and retain experienced management teams and qualified personnel to support our ongoing clinical development efforts, including at existing and 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;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- 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;
- defend against any product liability claims or other lawsuits related to our product candidates; and
- continue to meet the requirements of being a public company, including requirements under the Sarbanes-Oxley Act of 2002 ("SOX") and continue to protect our business operations and systems from cybersecurity threats.

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 current or future 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 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. In the event a product candidate fails to demonstrate a meaningful clinical effect or presents potential safety or tolerability issues in these early-stage studies, we may decide to discontinue development of the product candidate. In these cases, we generally will be unable to recoup any of the expenses associated with the acquisition or in-licensing of the product candidate or the costs associated with the studies. 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 the investment we made in developing 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.

Immunovant relies on the HanAll Agreement to provide the rights to the core intellectual property relating to IMVT-1402 and batoclimab. Any termination or loss of significant rights under the HanAll Agreement would adversely affect Immunovant's development and commercialization of IMVT-1402 and batoclimab.

Our subsidiary Immunovant holds the intellectual property rights to IMVT-1402 and batoclimab under a license agreement with HanAll Biopharma Co., Ltd. ("HanAll") (the "HanAll Agreement"). The HanAll Agreement imposes a variety of obligations on Immunovant, including those relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If Immunovant materially breaches any of its obligations under the HanAll Agreement and is unable to cure that breach within the time frame specified under the HanAll Agreement, Immunovant may be required to pay damages to HanAll and HanAll may have the right to terminate the HanAll Agreement, which would result in Immunovant being unable to develop or manufacture its products.

Biotechnology and pharmaceutical license agreements are complex and certain provisions in the HanAll Agreement may be susceptible to multiple interpretations. The resolution of any contract interpretation or disagreement that may arise could affect the scope of Immunovant's rights, or affect financial or other obligations, under the HanAll Agreement, either of which could harm our business, financial condition, results of operations and prospects.

Immunovant expects to report topline data from Phase 3 trials of batoclimab in thyroid eye disease in the second half of calendar year 2025. As previously disclosed, Immunovant will make a final decision about the future development and regulatory submissions for batoclimab in the future based on the aggregate information available at the time in consultation with our partner HanAll. HanAll has a variety of interests in the licensed products under the HanAll Agreement and outside of Immunovant's licensed territories, and may, as a result of those interests, disagree with, or initiate a dispute with respect to, Immunovant's development or commercialization plans for batoclimab. While the HanAll Agreement gives Immunovant final control over development and regulatory decisions relating to batoclimab in our licensed territories, to the extent HanAll disagrees with future development plans for batoclimab, they could initiate a dispute for alleged breach of the HanAll Agreement and the dispute may result in arbitration or litigation. While HanAll can assert breach at any time, we do not believe there is any basis for such a claim, and would vigorously contest such a claim if made. Any potential dispute with HanAll could be very expensive and time-consuming, may divert management's attention from core business functions and may result in unfavorable results that materially impact Immunovant's business.

We will likely incur significant operating losses for the foreseeable future and 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 in the near term. As a result, 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 June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $4.5 billion and our accumulated deficit was approximately $315.7 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. We expect to incur substantial operating losses for the foreseeable future, through the projected commercialization of our product candidates. 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 depend, in part, upon the size of the markets in the territories for which we 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 face risks associated with the allocation of capital and personnel across our businesses.

Because we have finite financial and management resources, we must 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 as a result. 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, decisions to delay or terminate certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. In addition, our management's attention to one product candidate or target indication may divert their attention from another opportunity or indication that ultimately might have proven more successful. If we do not accurately evaluate the commercial potential or target market for a particular product candidate or indication, or misinterpret trends in the biopharmaceutical industry more generally, we may relinquish valuable rights to a product candidate through collaboration, licensing or other royalty arrangements, or fail to pursue a target indication, which would have been more advantageous, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. In addition, our spending on current and future research and development programs and other future product candidates may not yield any commercially viable future product candidates.

We may pursue additional in-licenses or acquisitions of product candidates or programs, which entail additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial, legal and human resources expertise. Our efforts 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. 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, which 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, accounting systems and other policies 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. Additionally, certain officers or employees of Roivant may from time to time serve as officers or employees of the Vants. Such service by Roivant officers or employees may take away time or focus from such individuals' work at Roivant. Further, in their capacities as officers or directors of the Vants, 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.

The in-licensing transactions for our product candidates 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 acquisitions, divestitures and other strategic transactions.

We have in the past engaged in acquisitions, divestitures and other strategic transactions, and we may in the future pursue similar opportunities. For example, in October 2024 we completed the Dermavant Transaction, the consideration for which consisted of an upfront payment of $183.6 million and the AD Approval Milestone Payment of $75 million upon FDA approval of VTAMA for the treatment of atopic dermatitis. We received the AD Approval Milestone in January 2025. 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) 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 our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Any such future strategic transactions will entail numerous risks, including:

- in connection with divestiture or other sale or partnering transactions:
- the failure to realize the expected benefits from the transaction, including receiving milestone and royalty payments owed in connection with the transaction; and
- risks and uncertainties associated with the counterparty to any such transaction, including their ability to successfully develop and commercialize a product candidate such that milestone and royalty payments are triggered or their ability to make milestone and royalty payments when such payments are due;
- in connection with acquisition or in-licensing transactions:
- the risks generally applicable to biopharmaceutical drug development, including that the acquired or in-licensed program does not generate the expected clinical outcomes, that the expected timelines for the clinical program are delayed or otherwise slower than expected, that safety or tolerability issues arise in the clinical trials or that other regulatory issues arise, including the inability to receive regulatory approvals on the expected timelines or at all;
- the ability following applicable regulatory approvals to generate revenues from an acquired product candidate or program sufficient to meet our objectives or offset the associated transaction and maintenance costs;
- risks associated with the transfer or integration of the operations of an acquired entity or program, including difficulties associated with integrating any new personnel; and
- increased operating expenses and cash requirements, the assumption of indebtedness or contingent liabilities or the issuance of our equity securities in connection with such a transaction, which would result in dilution to our shareholders;
- the diversion of our management's attention from existing programs and other operational matters; and
- the loss of key employees and other uncertainties, including our ability to maintain key business relationships at the acquired entity, that may arise in connection with a given transaction.

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. 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.

As of June 30, 2025, we had cash, cash equivalents and marketable securities of approximately $4.5 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 the in-licensing of intellectual property, products, 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 even if such a transaction is identified, 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 macroeconomic and market trends and conditions, including volatility in the capital markets, and the other risks described herein.

As previously disclosed, in June 2025, our board of directors authorized a new common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to $500 million (excluding fees and expenses) (the "2025 Repurchase Authorization"). The 2025 Repurchase Authorization is in addition to the previously disclosed common share repurchase program allowing for repurchase of common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses), which was fully exhausted as of June 30, 2025. For the three months ended June 30, 2025, we repurchased 20.0 million common shares for an aggregate repurchase price of $205.2 million (based on the repurchase date).

The timing and total amount of any repurchases under the 2025 Repurchase Authorization, 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 and volatility, political risk, trade policy, including the imposition of additional tariffs, currency risk, credit risk, sovereign risk, interest rate fluctuations or other market or macroeconomic factors. Markets continue to be impacted by volatility, characterized by falling demand for a variety of goods and services, restricted credit, going concern threats to financial institutions, major multinational companies and medium and small businesses, poor liquidity, declining asset values, reduced corporate profitability, extreme volatility in credit, equity and foreign exchange markets and bankruptcies. 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 incurred 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.

While we do not have a need for additional capital under our current operating plans as a result of our current liquidity position, we may in the future require additional capital to fund our operations. In that case, if we fail to obtain necessary financing when needed, we may not be able to successfully acquire or in-license new product candidates, complete the development and commercialization of our product candidates following regulatory approval 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 we expect to continue to spend substantial amounts to fund our clinical development and other research and development activities, and to commercialize our product candidates following regulatory approvals. While we do not have a near-term need for additional capital under our current operating plan as a result of our current liquidity position, we may in the future 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 estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be available to fund our operations is based on assumptions that may be proven inaccurate, and we could exhaust our available capital resources sooner than we currently expect.

If adequate funds are not available to us in the future when we need it, we may be required to forego potential in-licensing or acquisition opportunities, delay, limit or terminate one or more development or discovery programs 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 approval and 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.

Unfavorable, uncertain and rapidly changing 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 changes in global or regional economic, political and public health conditions. Various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation levels, interest rates, international trade policies and tariffs and overall economic conditions and the current and future conditions in the global financial markets, including global or regional economic instability. For example, if sustained high rates of inflation or other factors were to significantly increase our expenses, we may be unable to manage such increased expenses or pass through price increases. During a severe or prolonged economic downturn, patients may prioritize other items over certain or all of their treatments and medications, which could have a negative impact on our commercial sales. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which economic climate and financial market conditions could adversely impact our business.

Additionally, uncertainties 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 (including current trade disputes with China), a global financial crisis, wars, terrorism, and civil unrest or could adversely affect our business. In particular, given the new administration in the United States, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, tariffs, treaties, taxes and other limitations on cross-border operations. The U.S. government has and continues to make significant additional changes in U.S. trade policies and tariffs and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or import goods or use services from existing service providers or become unable to export or, if approved, sell our products, our business, liquidity, financial condition and results of operations would be materially and adversely affected.

Further, outbreaks of disease (for example, COVID-19) and other unexpected public health events may cause extreme volatility in the capital and credit markets and other disruptions to our business. Business disruptions could include, among others, disruptions to our clinical development 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. 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.

A portion of our or certain of our Vants' manufacturing, laboratory research or clinical trial activities takes place in Asia. A significant disruption in that region, such as a trade war or political unrest, could materially adversely affect our business, financial condition and results of operations.

We and certain of our Vants currently engage and expect to continue to engage in contract manufacturing, conduct clinical trials, and perform laboratory research activities outside the U.S., including in Asia. Any disruption in production or inability of contracted manufacturers in Asia to produce adequate quantities to meet our or the Vants' needs could impair our or the Vants' ability to operate on a day-to-day basis and to continue development of certain product candidates. In particular, trade tensions and conflict between the United States and China remain high, and could result in changes to the laws, rules, regulations and policies of the governments of the United States or China that impact the ability of U.S. biotechnology companies to partner with entities in China. For example, starting in February 2025 the U.S. imposed additional tariffs on Chinese imports, and China has responded with tariffs on U.S. products. We or certain of our Vants also conduct certain laboratory research and expect to have clinical trial sites in Asia. We are exposed to the possibility of product supply disruption, clinical trial delays and increased costs in the event of changes in governmental policies, political unrest or unstable economic conditions in Asia. Any disruption of these activities could materially and adversely affect our business and results of operations.

Inadequate or uncertain funding levels for the FDA, USPTO, SEC or other government agencies could hinder, delay or result in the suspension of those agencies' operations, which could harm our business.

The ability of the FDA and other government agencies to review and approve new pharmaceutical products can be affected by a variety of factors, including budgets and funding levels, its ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Review times at the FDA have fluctuated in recent years as a result of changes in these factors. In addition, government funding of the SEC, USPTO and other government agencies on which our operations may rely or be dependent is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other government agencies may slow the time required for new drugs to be reviewed and approved, which could adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough employees and suspend certain activities. The Trump administration's freeze on hiring and new return-to-office policy may disrupt normal operations of federal agencies, including the FDA. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, or to provide feedback on our clinical development plans, which could have a material adverse effect on our business. There is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and regulatory approval process for our product candidates. Further, future government shutdowns or other disruptions to normal operations could impact our ability to access the public markets and obtain the funding necessary to properly capitalize and continue our operations.

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 ("E.U.") 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 E.U. 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 E.U., data derived from clinical trials that were conducted outside the E.U. 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 clinical trials and other studies may be delayed by several factors, including:

- the inability to generate sufficient data to support the initiation or continuation of clinical trials;
- difficulty identifying patients and enrolling them in clinical trials and other studies, including as a result of competing trials run by other pharmaceutical companies;
- the failure to add, or delays in activating, a sufficient number of clinical trial sites;
- the 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;
- the failure by our CROs or other third parties to adhere to clinical trial agreements;
- the 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;
- the inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;
- unforeseen safety issues, or subjects experiencing severe or unexpected adverse events;
- a lack of clinical benefit or effectiveness being demonstrated during clinical trials;
- the occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- premature discontinuation of study participants from clinical trials or missing data;
- the inability to monitor patients adequately during or after treatment;
- inappropriate unblinding of trial results;
- changes in the market that render continued development of a product candidate no longer reasonable or commercially attractive;
- the cost of clinical trials of our product candidates being greater than we anticipated;
- 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;
- the failure to obtain regulatory authorization to commence a clinical trial or reach consensus with regulatory authorities regarding the design or implementation of our studies;
- resolving any dosing issues, including those raised by the FDA or other regulatory authorities;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the approval policies or regulations of the FDA or other regulatory authorities;

- 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; or

- 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.

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. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the competent authorities of the E.U. Member States and the U.K. or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a clinical benefit from using a product candidate, changes in governmental regulations or administrative actions, developments on trials conducted by us or our competitors for related technology that raises regulatory concerns about risk to patients of the technology broadly, or lack of adequate funding to continue the clinical trial. 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 be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment and retention in our clinical trials for a variety of reasons, including:

- the size and characteristics of the patient population;

- the patient eligibility criteria defined in the protocol, including biomarker-driven identification and certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- the design of the trial, including the size of the study population required for analysis of the trial's primary endpoints;
- the number and location of clinical trials sites, including the proximity of patients to trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason, including the risk of higher drop-out rates if participants become infected with a virus or other infectious disease that impacts their participation in our trials.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays and retention challenges in our clinical trials may result in increased development costs for our product candidates, delay our ability to obtain clinical data, and jeopardize our ability to obtain marketing approval for the sale of our product candidates. For certain of our product candidates, including IMVT-1402, which target various 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 benefits sufficient to demonstrate that the efficacy endpoints of the study are met. Similarly, 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, preliminary or top-line data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or top-line data from our clinical trials, which are based on a preliminary analysis of then-available data. 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 interim, 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, interim, preliminary and top-line data should be viewed with caution until the final data are available. Interim data 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 interim, preliminary or top-line 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 our collaborators or 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 interim, preliminary or top-line data that we report differ from later, final or actual results, or if others, including our collaborators or regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates and 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 delays.

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.

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 regulatory authority may delay, limit or deny approval. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized. If we are unable to obtain regulatory approval in one or more jurisdictions for any of our 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 for commercial sale. 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.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidate involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary between jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

Changes to the leadership at the FDA and other federal agencies under the Trump administration, as well as executive orders and other executive actions, such as a freeze on hiring, the implementation of new regulations and certain external communications, may impact our clinical development and timelines. In particular, ongoing efforts by the Trump Administration to reduce the size of the FDA and other branches of the Department of Health and Human Services ("HHS"), including through reductions in staff, may further increase the unpredictability in approval timelines for our product candidates. For example, on February 11, 2025, President Trump issued an executive order on workforce optimization, seeking to reduce the size of the federal workforce through large-scale reductions in force and by placing limitations on the number of new employee hires. Pursuant to this executive order, on March 27, 2025, HHS announced that it was initiating a restructuring of the department, including reducing the FDA's workforce by approximately 3,500 full-time employees, which began on April 1, 2025. On July 8, 2025, the U.S. Supreme Court granted an application for a stay pertaining to an injunction entered by the U.S. District Court for the Northern District of California regarding the HHS reduction in staff, and on July 14, 2025, HHS emailed certain employees to notify them of their separation from HHS effective the same day. The termination of these employees has been preceded and accompanied by the resignation of senior leaders within the FDA, resulting in the loss of institutional knowledge and experience. Although the full impact of these events remains unclear, we expect there will be an adverse effect on the FDA's ability to efficiently carry out its functions, including conducting inspections and timely reviewing drug and biologic product applications, and a potential impact on how it interprets and enforces its authorities.

Contributing to this uncertainty, in June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gave deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, including the FDA, where the law is ambiguous. This landmark decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to greater uncertainty about the regulatory process in the pharmaceutical industry and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. Further, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Obtaining marketing approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process and the FDA or other 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;

- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- 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 labeling 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 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 product candidates 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.

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. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another set of patients or disease indications. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Open-label extension studies may also extend the timing and increase the cost of clinical development substantially. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and earlier stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

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 undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit the scope of any approved label or market acceptance following regulatory approval or result in significant negative consequences.

Adverse events caused by or associated with our product candidates have caused us and could, in the future, cause us, our collaborators, 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. 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. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or delay successful completion of clinical trials. Additionally, these side effects may not be appropriately recognized or managed by the treating medical staff. 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.

If one or more of our product candidates receives marketing approval, and we or others, including our collaborators, later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- 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 labeling statements, such as warnings or contraindications, require other labeling 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 labeling 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 particular product candidate, if approved, substantially increase the costs of commercializing our product candidates in the future following regulatory approval, and could significantly harm our business, financial condition, results of operations and growth prospects. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or clinical trials.

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 product candidates 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 product candidates will be harmed.

Following regulatory approvals, our products will remain subject to extensive regulatory scrutiny.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for manufacturing processes, post-approval clinical data, labeling, packaging, distribution, continuous supply, 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.

While healthcare professionals are free to use and prescribe drug products for off-label uses, the FDA and other foreign competent authorities strictly regulate manufacturers' promotion of drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the FDA-approved labeling. A company that is found to have improperly promoted off-label uses may be subject to large civil and criminal fines, penalties and enforcement actions. The same rules on off-label promotion apply in the E.U. and the U.K. If we cannot successfully manage the promotion of our approved product candidates, we could become subject to significant liability, which could materially adversely affect our business and financial condition.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. In certain indications, regulatory approval may limit the market of a product candidate to target patient populations when patient selection biomarkers are used. In these indications, regulatory authorities may require us to run additional clinical trials prior to expanding the label for approval that includes a broader patient population. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our non-biologic products or the safety, purity and potency of our biologic products, in general or in specific patient subsets. The Food and Drug Omnibus Reform Act reformed the accelerated approval pathway, such that the FDA is now required to specify conditions for post-approval study requirements and set forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things, issue warning letters, impose penalties, suspend regulatory approvals or require a product recall. Any of these actions by a regulatory agency could require us to expend significant time and resources, generate negative publicity and adversely affect the value of our company.

We may develop product candidates for the treatment of conditions for which there is little clinical experience and, in some cases, use new endpoints or methodologies, and the FDA or other regulatory authorities may not consider the endpoints of these clinical trials to provide clinically meaningful results.

There may not be any pharmacologic therapies approved to treat certain conditions that we attempt to address, and there may be few clinical trials attempted and no approved treatments for these conditions. As a result, the design and conduct of clinical trials of product candidates for the treatment of these conditions may take longer, be more costly or be more complicated to design due to the novelty of development in these conditions; and even if the FDA or other regulatory authorities do find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in our pivotal or other clinical trials. Further, even if we achieve the pre-specified criteria, our clinical trials may produce unpredictable or inconsistent results compared to the more traditional efficacy endpoints in the trial. As a result, achieving regulatory approval for such product candidates could be more uncertain, more costly and more time-consuming, which could adversely effect our business.

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 product candidates, 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, Good Laboratory Practices ("GLP") and Good Manufacturing Practices ("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 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. The FDA has also been issuing guidance documents regarding the accelerated approval pathway. 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.

The FDA also recently announced the Commissioner's National Priority Voucher and pilot program, designed to accelerate the development and review of certain drugs and biological products that are aligned with U.S. national health priorities and to enhance the health interests of Americans. Specific priorities include addressing a U.S. public health crisis, addressing a large unmet need and increasing affordability, among others. The pilot program is limited in scope: the FDA intends to select no more than five companies during the initial pilot year. Companies selected for the program will be issued a voucher entitling the company to benefits including enhanced communications and rolling review to allow for a shortened review time.

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 E.U. 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 E.U. 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 E.U. 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 E.U. 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. Further, in response to *Catalyst Pharms., Inc. v. Becerra*, a 2021 decision from the U.S. Court of Appeals for the Eleventh Circuit, the FDA clarified in a January 2023 notice that the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions and administrative actions will impact the scope of the orphan drug exclusivity.

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 E.U. Pharmaceutical Strategy, the European Commission published a proposal for a comprehensive revision of the E.U. 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 the end of 2025 at the earliest and it is expected to start to apply in 2027 or 2028.

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit). Thereafter, in March 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 in January 2020. A transition period began in February 2020, during which E.U. pharmaceutical law remained applicable in the United Kingdom. However, this ended in December 2020. In December 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 that time, Great Britain operated a separate regulatory regime for medicinal products, although Northern Ireland continued to follow E.U. law. Further, in March 2023, an agreement was reached by the U.K. and E.U. (the "Windsor Agreement"), relating to post-Brexit trade issues in Northern Ireland, which has applied from January 2025. This seeks to simplify the supply of medicines between Great Britain and Northern Ireland and means E.U. legislation does 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 E.U. 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 E.U. 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., in particular in relation to the clinical trials and medical devices frameworks in the U.K.

Following Brexit, a separate process for orphan drug designation applies to the U.K. 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 the U.K. only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in the U.K.). Following the application of the Windsor Agreement on January 1, 2025, authorization of orphan products by the MHRA covers the whole of the U.K.

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 or MHRA can subsequently approve the same drug for a different condition or the same condition if the FDA or the EMA or the MHRA 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 and U.K., 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 E.U. pharmaceutical legislation, as discussed above.

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 our product candidates will depend on a number of factors, including:

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

Even if a product candidate displays a favorable efficacy and safety profile in clinical trials, market acceptance will be unknown until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

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

The Affordable Care Act 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 product candidates, 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. Our product candidates approved as a biological product under a BLA may 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 product candidates, 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, healthcare 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 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 clearinghouses, 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 E.U. 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 enforcement under the federal False Claims Act, and certain local and state laws that require disclosures to state agencies or boards and commercial purchasers, for example, with respect to certain price increases, some of which contain ambiguous requirements that government officials have not yet clarified; and

- E.U. 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 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 labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Moreover, as discussed above, the removal of the Richardson Waiver may impact our ability to meaningfully engage in any rulemaking for which HHS does not engage in the notice-and-comment process.

Additionally, the Trump Administration may pursue new or different drug pricing, trade and tariff, social and other policy objectives from prior administrations, which introduces further uncertainty as to how future legislative or regulatory changes may impact our business. For example, within his initial days in office, President Trump issued an executive order repealing former President Biden's executive order 14087, which directed the Centers for Medicare and Medicaid Services ("CMS") Center for Medicare and Medicaid Innovation to test new payment models that would lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries. In addition, the Trump Administration published an executive order 14273 titled "Lowering Drug Prices by Once Again Putting Americans First." Generally, this executive order instructs HHS to recommend ways to lower drug prices. The Trump Administration also renewed the idea of international referencing pricing through the May 2025 executive order 14297 titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients." Among other things, this executive order directs the Secretary of HHS to communicate most-favored-nation price targets to manufacturers and propose a rulemaking plan to impose most-favored-nation pricing if "significant progress" is not made towards achieving such pricing. It also states that the Administration will take additional aggressive action should manufacturers fail to offer American consumers the most-favored-nation lowest price. It is not clear if and how these executive orders will impact our business. It also is possible that specific related, subsequent actions and/or proposals are forthcoming. Additionally, President Trump also took executive action to end diversity, equity and inclusion initiatives among public-sector contractors and grantees. Moreover, the Trump Administration is prioritizing efforts to restructure HHS, including substantial reductions in workforce. It is not clear how this restructuring of HHS will impact our business. Finally, the Trump Administration has imposed broad tariffs on foreign imports, which in many cases has caused other nations to levy reciprocal tariffs on goods manufactured in the United States. It also is possible that specific tariffs on pharmaceuticals are forthcoming. These measures could impact our costs for raw materials and manufacturing as well as the market for our future products. Some of these policy changes may be subject to litigation, increasing the uncertainty of their effects on our business.

There has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Notably, 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. 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. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial changes, future litigation brought in view of the Supreme Court's overrule of the Chevron doctrine, legislative, executive and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear.

There also have been and continue to be a number of other 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.

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. Moreover, the Trump Administration may renew its prior proposals to establish price caps based on pricing in foreign countries or pursue other pricing initiatives that tie drug prices in the United States to those available abroad. 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.

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 have generally taken effect since 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. On July 14, 2025, CMS issued a Medicare Physician Fee Schedule proposed rule, which if finalized, would, among other things, restrict whether certain fees should be considered bona fide service fees, increase bona fide service fee documentation requirements, define "bundled arrangement," require "unbundling" of both contingent and non-contingent discounts and include sales of Part B units at the Maximum Fair Price in average sales price calculations. These changes, if finalized, could lower reimbursement for Medicare Part B utilization and require manufacturers to comply with new, uncertain or complex reporting obligations and drug pricing documentation practices.

Moreover, upcoming legislative and policy changes in the E.U. 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 E.U. 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 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; and
- the amount of taxes that we are required to pay.

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. Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs. Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, pharmacy benefit managers and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products, particularly our therapeutic products or those that are individualized for a particular patient.

We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular drugs. Target patient populations for some of our product candidates may be small. The pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. 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. The manner, level and specific type of reimbursement provided for services related to patients is also important. Inadequate reimbursement for such services may discourage physicians from prescribing or recommending our product candidates, if approved, adversely affecting our ability to market or sell those products.

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. For example, a budget resolution passed the U.S. House of Representatives in February 2025 to reduce the federal deficit by at least $880 billion over 10 years and the majority of these cuts are expected to impact Medicaid and CHIP if enacted into law. These cuts could involve reducing the scope of coverage under Medicaid and CHIP, including as it relates to prescription drug benefits. 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. Separately, President Trump signed into law the One Big Beautiful Bill Act on July 4, 2025, which is expected to impact Medicaid and other government entitlement programs. In addition, other changes and proposals enacted by and under consideration by state and local governments to Medicaid and other government assistance and entitlement programs also may impact our business.

Our ability to set the price for any product we develop will vary significantly by country. Our inability to obtain and maintain adequate prices in a particular country may limit the revenues from our products, if approved, within that country and adversely affect our ability to secure acceptable prices in existing and potential new markets, which may limit market growth. This may create the opportunity for third-party cross-border trade or influence our decision whether to sell a product, thus adversely affecting our geographic expansion plans and revenues. In the E.U., 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 E.U. or the E.U. Member States may harm our ability to profitably sell our product candidates following regulatory approval. The delivery of healthcare in the E.U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national E.U. 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. Similarly, provisions have been introduced into the parallel statutory scheme, which applies to companies that are not members of the voluntary scheme, and will lead to higher rebates than previously. In markets outside of the U.S., E.U. 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 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, a 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.

Risks Related to Our Reliance on Third Parties

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, clinical data management organizations, medical institutions and clinical trial sites to conduct some aspects of our research and preclinical testing and to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities. In addition, we rely upon CROs to monitor and manage data for our clinical programs, as well as for 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.

Our third-party service providers are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These third-party service providers 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 that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We and our CROs are required to comply with 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.

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 regulatory 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; this may include the imposition of tariffs on foreign-manufactured products that we procure. 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 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 following regulatory approval, 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 revocations, suspensions 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 regulatory approval, commercial supplies for those product candidates.

We and 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 may not have produced a commercially approved pharmaceutical product and therefore may not have 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 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 regulatory 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.

We may be dependent on one or a limited number of suppliers for certain components of our product candidates.

For certain of our product candidates, we may now or in the future be dependent on one or a limited number of third-party suppliers for our product candidates. We cannot ensure that such suppliers will be available or have sufficient capacity or supply to meet our needs, or that they will not be acquired by a competitor and cease working with us as a result. As a result, we face a number of related risks, including disruptions or delays in the supply of our product candidates or price fluctuations for those supplies.

From time to time, there may be a limited number of potential suppliers for our product candidates. If we were required to change suppliers, the manufacture and delivery of our product candidates could be interrupted for an extended period of time. Establishing additional or replacement suppliers for any of the components or processes used in our product candidates, if required, may not be accomplished quickly, if at all. Any replacement supplier would need to be qualified and may require additional regulatory approval, resulting in further delay. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could limit the supply of our product candidates available for use in clinical trials or commercial sale following applicable regulatory approvals. Additionally, the FDA, as part of its evaluation of our product candidates, will review the manufacturing processes and facilities of our suppliers. Any delay, or failure to receive, such approval, including as a result of delays in the FDA review of our suppliers, could delay or prevent the approval of our product candidates.

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 novel, complex 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 candidate may not be sufficient to ensure that the product candidate 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 candidate 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 E.U., 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 candidate 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 candidate 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.

We are subject to operational risks associated with the physical and digital infrastructure at the manufacturing facilities that our external service providers utilize.

The manufacturing facilities we rely on may incorporate a significant level of automation of equipment with integration of several digital systems, including those that may utilize AI, to improve efficiency of operations. The digitization of these facilities exposes us to the risk of process equipment malfunctions. These risks include potential system failures or shutdowns due to internal or external factors including design issues, system compatibility or potential cybersecurity compromises, incidents or breaches. Upgrades or changes to these systems, infrastructure or the software that our external service providers implement, use, or upon which our business relies, may result in the introduction of new cybersecurity vulnerabilities and risks.

The facilities and infrastructure of our contract manufacturers or other third-party providers may also be subject to attacks or acts of sabotage by outside actors, contractors or employees. Any disruption in our contract manufacturers' manufacturing capabilities could delay scaling up production capacity for our product candidates or shut down facilities, impose additional costs, cause us to fail to meet certain product volume or delivery timing obligations, or may require us to identify, qualify and establish an alternative manufacturing site, which could adversely affect our business.

Other Risks Related to Our Business and Industry

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical, financial, accounting and legal 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. The loss of the services provided by any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business. 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 addition, we rely on a limited number of employees in certain key jurisdictions, including the U.K. and Switzerland. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. 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.

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. Our employment agreements provide that our employees could leave our employment at any time. We do not maintain "key person" insurance for any members of our senior leadership team or other employees. 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. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

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 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 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.

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.

There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could harm our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

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, biotechnology companies, academic institutions, government agencies and other public and private research organizations worldwide. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and product candidates.

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

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 regulatory approval for their products more rapidly than we do 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 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 future products.

The markets in which our healthcare technology and computational drug discovery 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 Zest, which is building a medical dermatology platform, 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, payors, providers and other software and services vendors. Our computational drug discovery Vants, including VantAI, which uses machine learning to build computational models to generate new molecular entities for targets of interest, and Psivant, which uses molecular dynamics to design small molecules for highly validated hard-to-drug targets, face competition from both established industry competitors and an increasing wave of competition in the in silico discovery and development worlds, including startups, large and mid-sized biopharmaceutical companies, large technology companies and others. Our computational drug discovery companies develop highly specific technologies designed to accelerate the process of drug discovery. We have no assurance that our technologies will perform as expected, and new and existing competitors from academia, the startup ecosystem or established biopharmaceutical companies may already have or will develop more performant technology. The field is growing rapidly and more and better funded competitors will continue to enter our markets and innovate.

Many of our healthcare technology 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, and may generally have more effective relationships with key healthcare stakeholders, including payors, providers, regulators and other software and services vendors, among others. If our competitors' products, services or technologies are more capable or become more accepted than our solutions, if our competitors are successful in bringing their products or services to market earlier than we do or if our competitors are able to respond more quickly and effectively to new or changing opportunities, technologies or customer requirements than we can, then the business and prospects of these Vants could be adversely affected.

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, in both healthcare technology and drug discovery.

Some of these competitors are involved in drug discovery (either themselves 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. Any of these risks, if encountered, could negatively impact our financial condition, results of operations and cash flows.

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, product liability claims related to our clinical trials, 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 internal computer and other information technology systems, or those used by our collaborators, CROs or other contractors, consultants or third parties upon whom we rely, may fail or suffer other breakdowns, cyberattacks or information security breaches or incidents, including as a result of a deficiency in our cybersecurity practices, that could compromise the confidentiality, integrity and availability of such systems and data, expose us to liability and affect our reputation.

We are dependent upon information technology systems, infrastructure and data to operate our business. We also rely on third-parties and their information technology systems. 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. Despite the implementation of security measures, our internal computer and other information technology systems and those of our collaborators, CROs and other contractors, consultants and third parties upon whom we rely may be vulnerable to damage, outages and interruptions resulting from computer viruses and other malicious code or unauthorized access, or breached, compromised or otherwise subject to security incidents due to operator error, inadvertent or intentional actions by our employees or other third parties, malfeasance, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, telecommunication and electrical failures or other system disruptions. Geopolitical events, such as wars and other conflicts, may increase the risks of cyber-attacks, disruptions and security breaches and incidents that we and these third parties face. Security threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be broad-based or otherwise generic in nature, or they may be custom-crafted against our information technology systems or those of our collaborators, CROs or other contractors, consultants or third parties upon whom we rely.

As the cyber-threat landscape evolves, cyber-attacks have become more prevalent, intense, sophisticated and much harder to detect and defend against. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering, including phishing attacks, and other means. We and our collaborators, CROs or other contractors, consultants and third parties upon whom we rely may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources. Although to our knowledge we have not experienced any such material system failure or security breach or incident to date, if a breakdown, cyberattack or other information security breach or incident were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to loss or misappropriation of trade secrets or loss of, or unauthorized modification, unavailability, disclosure or other unauthorized processing of, other proprietary information or other similar disruption, and we could incur liability and reputational damage. For example, any corruption, loss or other unavailability of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer and other information technology systems could also have a material adverse effect on our business.

Cyber-attacks, breaches, interruptions or other data security incidents could result in legal claims or proceedings by private parties or governmental authorities, liability under federal or state laws that protect the privacy of personal information, regulatory penalties, significant remediation costs, disruption of key business operations and diversion of the attention of management and key information technology resources. In the United States, notice of breaches must be made to affected individuals, the HHS, and for extensive breaches, notice may need to be made to the public at large or U.S. state attorneys general. Such a notice could harm our reputation and our ability to compete. In addition, U.S. state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. There can be no assurance that we, our collaborators, CROs, contractors, consultants and any other business counterparties will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all break-downs, service interruptions, attacks or security breaches or incidents. Although we maintain insurance protection against cybersecurity events or incidents, the costs related to significant security breaches, incidents or disruptions could be material and exceed the limits of any insurance coverage we have, and may result in increases in our insurance costs, or we may otherwise 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. Relevant insurance may in the future become unavailable to us on commercially reasonable terms or at all. Any disruption or security breach or incident that results in or is perceived to have resulted in a loss of, or damage to, our data or systems, or inappropriate disclosure, use, acquisition, transfer, modification, unavailability or other processing of confidential or proprietary information, including data related to our personnel, could result in the loss, unauthorized modification, use, unavailability, disclosure or other unauthorized processing of critical or sensitive data, and could cause us to incur liability. Further, in any such event, the development and commercialization of our product candidates following regulatory approval could be delayed and our business and operations could be adversely affected. Any of the foregoing could result in significant financial, legal or reputational harm to us and our business.

Our business is subject to complex and evolving U.S. and foreign laws and regulations, information security and other policies, and contractual obligations relating to privacy and data protection and security, including the use, processing and cross-border transfer of personal information. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business, as could any actual or perceived failure by us or third parties upon whom we rely to comply with such laws and regulations and other obligations.

Certain of our subsidiaries and affiliates collect, receive, store, and otherwise process significant and increasing volumes of personal data (including protected health information), research and developmental information, commercial information, and business and financial 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 heavily rely on external security and infrastructure vendors to manage our information technology systems and data centers. We face a number of risks relative to protecting this critical information, including the loss of access, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to third-party vendors and subcontractors we use to manage this sensitive data.

We are subject to data privacy and protection laws and regulations governing 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 such information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. A failure by us, our subsidiaries or affiliates or vendors acting on our behalf 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. 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, which vary from state to state, 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.

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 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. Several U.S. states have enacted (as discussed further below) legislation specifically to regulate the collection, use, and disclosure of personal health information by entities not subject to the HIPAA privacy and security regulations. Other states have enacted laws that, while not specifically focused on personal health information, require heightened protections for that information to the extent it is not regulated by HIPAA. Given that we are generally not subject to HIPAA, these laws require us to invest in compliance resources and create liability risks for us.

The Federal Trade Commission ("FTC"), along with certain state attorneys general, have taken aggressive action to protect consumers' privacy and the use of consumer personal information. Using its authority under Section 5 of the FTC Act, which prohibits unfair and deceptive practices affecting consumers, the FTC has brought numerous cases against companies for failing to protect the privacy and security of personal information in a manner 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.

More than twenty U.S. states have enacted new privacy legislation in recent years and amended existing laws to address privacy risks posed by new technologies. With respect to personal information, for example, the California Confidentiality of Medical Information Act (the "CMIA"), which expressly applies to pharmaceutical companies as well as health care providers and health plans, provides protection for personal health information stored in mobile applications and similar technologies and imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA, with limited exceptions, requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information and requires the company 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 for violations made 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 apply broadly to entities collecting personal health information either within the state or about residents of the state, generally require consent for the collection and use of such 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.

More broadly applicable state consumer privacy 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, among other things, limit the use and disclosure of their "sensitive" (including health) personal information other than for specified purposes and the ability to opt-out of certain sales of personal information. Most of the broadly applicable state privacy 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. Numerous other states in the United States have proposed or enacted similar legislation. Further, some states have enacted more specific legislation, such as Washington's enactment of the My Health, My Data Act, which includes a private right of action. The U.S. federal government is also contemplating federal privacy legislation. Additionally, the U.S. Department of Justice recently issued a final rule that took effect in April 2025 and places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China or with other specified links to China (and other designated countries).

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 the E.U. the collection and use of personal data is governed by the provisions of the E.U. 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 E.U. 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 E.U.-US Privacy Shield was such a transfer mechanism put in place by the E.U. 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 E.U.-U.S. Data Privacy Framework ("DPF") was since developed. In July 2023, the U.S. and E.U. implemented the DPF. Companies can now use this new mechanism to transfer personal data from the E.U. to the U.S. and from Switzerland to the U.S., following the national implementation in Switzerland. The U.K. Extension to the E.U.-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. It is also unclear whether actions by the Trump Administration will lead the European Commission to reconsider the DPF. Related questions were raised in the European Parliament in the beginning of 2025.

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 E.U. 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 E.U. 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 E.U. Member State in question and the competent authority bringing the claim is not the lead supervisory authority.

Further, as of January 1, 2021, and the expiry of transitional arrangements agreed to between the U.K. and the E.U. (*i.e.*, following the U.K.'s exit from the E.U.), 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 substantial 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 E.U. 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 June 2025, the U.K. adopted a reform of the data protection and e-privacy legislation intended to create a more business-friendly regime in the U.K. and increase fines for e-privacy breaches. At this stage it is unclear whether this legislative reform would potentially lead the European Commission not to extend or to revoke the U.K. adequacy decision. On March 18, 2025, the European Commission proposed to extend its adequacy decision in favor of the U.K. for an additional six-month period. This would allow transfers of personal data from the E.U. to the U.K. to continue until December 27, 2025 and is intended to allow time for the European Commission to assess the new U.K. legal framework and decide on its adequacy. In the meantime, the U.K. data protection rules that were found adequate in June 2021 remain in place and continue to apply to data transferred from the E.U.

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, E.U. 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.

If we or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors or potential collaborators fail to comply with healthcare laws or regulatory standards and requirements, we could face substantial penalties and our business, operations, and financial conditions could be adversely affected.

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. The laws that may impact our operations include the federal Anti-Kickback Statute, the False Claims Act, the HIPAA, as amended by HITECH, the federal Physician Payment Sunshine Act, federal consumer protection and unfair competition laws and analogous state and foreign laws and regulations. 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.

If product liability claims are brought against us, we may 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. We may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates following regulatory approval. Even successful defense would require significant costs to defend litigation and a diversion of management's time and resources. Regardless of the merits or eventual outcome, liability claims may result in a decreased or interrupted demand for our product candidates, if approved, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, and initiation of investigation by regulators. Any successful liability claims could result in substantial monetary awards to trial participants or patients; product recalls, withdrawals, or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate following regulatory approval; and a decline in our share price.

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. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. 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 or any contract manufacturers or suppliers we engage 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, hurricanes, fires, 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, hurricanes, fires 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 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.

We and 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 E.U. Artificial Intelligence Act (the "E.U. AI Act"), which establishes broad obligations for the development and use of AI-based technologies in the E.U. based on their potential risks and level of impact, came into force. The E.U. 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. Moreover, on July 7, 2025, the European Commission published draft GMP guidelines on the use of AI in manufacturing of medicinal products in the E.U. These guidelines exclude the use of generative AI, large language models (LLMs), dynamic AI models and AI models with probabilistic outputs from critical GMP functions. 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 or working with our licensors to file 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 products, 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, held unpatentable, 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 of our product candidates or other technology 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 or otherwise find an issued patent to be unpatentable. 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 patentability, validity, enforceability or scope, which may result in such patents being narrowly construed, invalidated or held unenforceable or unpatentable, 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 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 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 own or have in-licensed with respect to our product candidates fail to issue, if their validity, patentability, enforceability, 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.

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 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 patent rights and other intellectual property rights to the same extent as the state and federal 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 in-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, patentability, 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.

The issuance of a patent is not conclusive as to its inventorship, scope, patentability, 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, re-examination, *inter partes* review ("IPR"), post-grant review or interference or derivation 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.

Certain U.S. patents relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that GSG, 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 Patent Trial and Appeal Board ("PTAB"), whose decisions were subsequently reviewed by the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit"). As previously disclosed, with respect to two of these patents, the Federal Circuit ultimately affirmed the PTAB's decisions upholding certain claims under those patents and invalidating others; and, with respect to the third patent, the Federal Circuit dismissed Moderna's appeal. Additionally, one European patent (EP 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 ("Merck") 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 an appeal hearing is scheduled for January 2026. Genevant may commence litigation at any time to enforce its patent rights against infringers. Additionally, a European patent (EP Patent No. EP4241767 B1) relating to certain ionizable lipids that Genevant exclusively licensed from Arbutus is the subject of an opposition proceeding brought in 2025 by Moderna at the EPO. The opposition is pending.

The outcome following legal assertions of unpatentability, 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 regulatory 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 patentability, validity, 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 in patent claims being narrowed, invalidated or held unenforceable or unpatentable, in whole or in part, which could limit our freedom to operate, our ability to stop others from using or commercializing similar or identical technology and product candidates, or 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 in-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 statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. 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 in-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 statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In 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 in-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 rights and other intellectual property rights 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. Patent term extension also may be available in certain foreign countries, including the E.U. where it is known as a Supplementary Protection Certificate, upon regulatory approval of our product candidates, based on similar legislation. 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, underpayment or non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. 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, and will continue to be dependent, on licenses to patent rights and other intellectual property granted to us by third parties. Further, development and, following regulatory 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, biotechnology and pharmaceutical license agreements are complex and 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 may 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 in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and, following regulatory 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 regulatory 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. Our subsidiary Immunovant has licensed certain intellectual property rights under the HanAll Agreement. We and Immunovant depend, and will continue to depend, on the HanAll Agreement for the rights to develop, manufacture and commercialize certain product candidates. We and Immunovant face risks under the HanAll Agreement, including that if, for any reason, the rights granted to Immunovant under the HanAll Agreement are terminated or Immunovant otherwise loses the rights granted under that agreement, it would adversely affect our and Immunovant's business. For more information regarding the risks associated with the HanAll Agreement, please see "Immunovant relies on the HanAll Agreement to provide the rights to the core intellectual property relating to IMVT-1402 and batoclimab. Any termination or loss of significant rights under the HanAll Agreement would adversely affect Immunovant's development and commercialization of IMVT-1402 and batoclimab" above.

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 regulatory 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 our licensor 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, enforcement 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, enforce and defend the in-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 regulatory 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 E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America, as such rights in other jurisdictions have been retained by 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, even if such litigation or administrative proceeding occurs in a territory in which we do not have a license. 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, and will continue to depend, 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 infringe 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 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 wilfully 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 or are finally determined to be invalid or unenforceable or unpatentable. 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 regulatory approval, commercialize the applicable product candidate, unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable or unpatentable. 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 us, we may have to pay substantial damages, including treble damages and attorneys' fees for wilful 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 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 unpatentable, 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 covering our product candidates or their methods of manufacture or use, 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 GSG and its affiliate 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 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 in favor of GSG and Arbutus. In February 2024, the court held a claim construction hearing on disputed terms within the claims of the asserted patents. In April 2024, the court provided its claim construction ruling, in which it construed the disputed claim terms and agreed with GSG and Arbutus' position on most of the disputed claim terms. Both fact discovery and expert discovery in the Moderna Action have been completed. In June 2025, the court issued a new scheduling order in the case. In accordance with that order, the parties served their respective summary judgment motions in July 2025. In addition, also in July 2025, the case was reassigned to a different judge in the same federal district court. The jury trial in the Moderna Action is scheduled for March 2026.

Separately, in April 2023, GSG 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 court held a claim construction hearing in the Pfizer Action in December 2024. The court has not provided guidance for the timing of its ruling in the claim construction ruling, which could potentially come in calendar year 2025.

In addition, in March 2025, GSG and Arbutus filed five international lawsuits against Moderna targeting alleged infringing activity in 30 countries (the "International Cases"). These cases are:

- Canada: Federal Court of Canada File No. T-704-25, seeking a permanent injunction and damages or, if GSG so elects, an accounting of Moderna's profits, attributable to infringement of Canadian Patent No. 2,721,333.

- Japan: Tokyo District Court Case No. 2025 (Wa) 70079, seeking a permanent injunction and reasonable royalty for infringement of Japanese Patent No. 5,475,753.

- Switzerland: filing a case, seeking a permanent injunction and monetary relief, which upon later choice of GSG and Arbutus can include surrender of profits, damages or a reasonable royalty, for infringement of EP 2 279 254.

- Unified Patent Court ("UPC"): Case 10280/2025, seeking permanent and provisional injunctions, as well as monetary damages, which can include recovery of Moderna's unfair profits, for infringement of EP 2 279 254.

- UPC: Case 10284/2025, seeking permanent and provisional injunctions, as well as monetary damages, which can include recovery of Moderna's unfair profits, for infringement of EP 4 241 767.

The UPC actions together seek relief in the following countries: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland/Liechtenstein and Turkey.

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, the International Cases, 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 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 unpatentable, 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 as well as for double-patenting. 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 or that inventorship of the patent was incorrectly named. Third parties may also raise similar validity or unpatentability 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 unpatentability, 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 in-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 unpatentability, 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, if approved, 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 International Cases, 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, if approved, 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 in-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, we depend and will continue to depend 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 in the past and more 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 and U.S. Court of Appeals for the Federal Circuit have 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 future 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 future 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 future 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 biotechnology and pharmaceutical 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 or pharmaceutical 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 intellectual property 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 and information 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 or know whether the steps we have taken to protect our intellectual property will be effective. 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. The enforceability of confidentiality agreements may also vary from jurisdiction to jurisdiction. 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. 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 or distribution 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 including patent rights and copyrights. 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 or distribution 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. We may also face claims alleging that the contractual terms of an open source license provide the licensor with an ownership interest in our developments made using software that incorporates the open source code. 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, consultants, independent contractors 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 in-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, and will continue to 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, consultants, independent contractors, 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, independent contractors 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, consultants, independent 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, and will continue to 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 the granted claims may be finally determined to be unpatentable, invalid or unenforceable 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 products 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 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.

The use of AI by us, our early-stage discovery Vants and our healthcare technology businesses may introduce intellectual property risks.

The use of AI by us, our early-stage discovery Vants and healthcare technology businesses may introduce intellectual property risks that may adversely affect our ability to protect and commercialize our innovations. As part of our business strategy, we and certain of our Vants integrate AI-driven technologies into various stages of research and development processes, including target identification, drug discovery, compound screening, and clinical trial optimization. The use of generative AI algorithms, particularly those that autonomously generate data, models, or potential therapeutic candidates, raises unresolved legal questions about inventorship and ownership under current patent laws in the United States and other jurisdictions. Patent offices, including the USPTO, have yet to adopt a consistent framework for determining inventorship of AI-generated inventions. If we are unable to establish that our employees or systems meet the legal criteria for inventorship, we may be unable to secure patent protection for certain innovations developed using AI. Inability to protect such AI-generated inventions may diminish our competitive advantage and allow others to compete with us, harming our business. Obtaining and enforcing intellectual property protection for AI-generated outputs, such as product candidates or clinical trial designs, also presents risks to our business. If we are found to have used data in a manner inconsistent with applicable laws or agreements, we could face legal claims, ownership disputes, invalidation of our intellectual property rights, or restrictions on the use of our AI models. If we are unable to secure, maintain, and enforce effective intellectual property protection for our AI-enabled innovations, our business may be harmed. If we become subject to significant intellectual property litigation or licensing restrictions based on our use of AI tools, our ability to achieve or sustain a successful business may be materially harmed. Our use of AI in these processes may involve several intellectual property risks that may materially impact our business, financial condition, 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;
- 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, tariffs and trade conditions in the global economy, commodity 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 June 30, 2025, 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.

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 the removal of management more difficult 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 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. On March 31, 2025, the board of directors deferred the annual increase in the shares available for issuance under the 2021 EIP to one or more later dates prior to March 31, 2026. To the extent the board of directors later approves 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 other corporate uses 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 be subject to U.S. federal income taxation on our undistributed earnings.

A non-U.S. corporation is considered a "controlled foreign corporation" ("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 for taxable years beginning before December 31, 2025, a portion of the CFC's "global intangible low-taxed income" (commonly known as "GILTI"). The One Big Beautiful Bill Act provides that, among other things, the GILTI regime be replaced with a similar regime with respect to a CFC's "net CFC tested income" for taxable years beginning after December 31, 2025. 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. GILTI may include most of the remainder of a CFC's income over a deemed return on its tangible assets, and "net CFC tested income" generally is similar to GILTI, but is computed without accounting for any such deemed return on a CFC's tangible assets.

We believe that we were not classified as a CFC for the taxable year ended March 31, 2025. Regardless of whether we are a CFC, however, our non-U.S. subsidiaries will be classified as CFCs for the taxable year ended March 31, 2025 because our U.S. subsidiaries are treated as constructively owning the stock of such non-U.S. subsidiaries pursuant to a "downward attribution" rule under current law (when not directly owned by a U.S. subsidiary). Following the enactment of the 2025 Tax Act, this rule generally will cease to apply to treat such non-U.S. subsidiaries as CFCs for taxable years beginning after December 31, 2025 other than in certain limited circumstances. Accordingly, 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 GILTI or net CFC tested income 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, including as a result of the enactment of the 2025 Tax Act.

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, 2025, 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, 2025, 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 months ended June 30, 2025, we repurchased 19,999,450 common shares for $205.2 million (based on the repurchase date). As of June 30, 2025, we were authorized to repurchase up to $500 million of our common shares (see footnote 1 to the table below).

The following table summarizes our common share repurchase transactions for the three months ended June 30, 2025:

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 Programs(1)	Approximate Dollar Value of Common Shares that May Yet Be Purchased Under the Programs(1)
				(in millions)
April 1 – 30, 2025	13,672,384	$ 9.89	13,672,384	$ 69.9
May 1 – 31, 2025	5,453,666	$ 11.04	5,453,666	$ 9.7
June 1 – 30, 2025	873,400	$ 11.16	873,400	$ 500.0
Total	19,999,450		19,999,450	

(1) 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). On June 25, 2025, we announced that our board of directors had authorized an additional common share repurchase program of Roivant common shares of up to $500 million (excluding fees and expenses). This new authorization is in addition to the $1.5 billion common share repurchase program referenced above, which was fully exhausted as of June 30, 2025. The timing and total amount of common shares repurchased under the new authorization, as with the prior authorization, depends on several factors, including the market price of our common shares, general business, macroeconomic and market conditions and other investment opportunities. Under the new repurchase program, as with the prior 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 three months ended June 30, 2025, we withheld 879,308 common shares associated with net share settlements to cover tax withholding obligations upon the vesting and settlement of equity incentive awards issued under our equity incentive plans, including RSUs and CVARs.

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
10.1^	Letter of Offer for Employment between Roivant Sciences, Inc. and Jennifer Humes, dated as of February 7, 2025.	—	—	—	Filed herewith
10.2†^	Amended & Restated Executive Employment Agreement between Roivant Sciences, Inc. and Eric Venker, dated as of July 28, 2025.	—	—	—	Filed herewith
10.3^	Employment Agreement between Immunovant, Inc. and Eric Venker, dated as of July 28, 2025.	—	—	—	Filed herewith
10.4^	Form of Capped Value Appreciation Right Award Grant Notice and Award Agreement under 2019 Equity Incentive Plan of Immunovant, Inc.	—	—	—	Filed herewith
10.5^	Forms of Option Grant Notices and Option Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3.1	June 29, 2020
10.6^	2019 Equity Incentive Plan of Immunovant, Inc.	10-K	001-38906	10.3	June 29, 2020
10.7†^	Special Equity Award Opportunity Letter, dated as of July 26, 2024.	—	—	—	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 registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

^ Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-Q pursuant to Item 15(b).

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: August 11, 2025

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/ Keyur Parekh
Name: Keyur Parekh
Title: Authorized Signatory

Exhibit 10.1

02/07/2025

Dear Jenni,

Welcome to Roivant Sciences, Inc. (Roivant), where we build and launch healthcare companies in biotechnology and life sciences. Roivant is focused on value creation, and our people are our most valuable asset. We believe that you will make significant contributions to Roivant's growth and success, and are excited to extend this employment offer based on the terms outlined below.

Here are the details of your offer:

Position:	Chief Accounting Officer
Reporting To:	Richard Pulik, Chief Financial Officer Accounting
Department:	Accounting
Target Start Date:	02/20/2025
Roivant Work Assignment:	Hybrid - New York Office
Annual Salary:	$380,000
Sign-on Bonus:	$261,500
Target Annual Cash Bonus:	$190,000 (50%)
Target Annual Total Compensation:	**$570,000**
Onboarding Equity Grant:	You will be eligible for a grant of a number of restricted stock units relating to common shares of our parent company, Roivant Sciences Ltd. ("RSL") (Nasdaq: ROIV) (the "RSU Grant"), that will have an aggregate estimated cash value as of the grant date of approximately $1,200,000. The actual number of restricted stock units to be granted to you will be determined as of the grant date by dividing the foregoing aggregate estimated cash value by the fair market value per common share of RSL as of the grant date, as determined by RSL and calculated by reference to the public trading price of RSL's common stock prior to the grant date (using either a spot or average trading price, as determined by RSL).

You will be eligible for a grant of a number of options to purchase common shares in RSL ("Grant Option" and together with the RSU Grant, the "Onboarding Equity Grant"), that will have an aggregate estimated "Black- Scholes" value as of the grant date of approximately $800.000. The actual number of options to be granted to you will be determined as of the grant date by dividing the foregoing aggregate estimated cash value by the most recent value of a single option of Roivant Sciences Ltd., in effect as of the grant date, as calculated by RSL using a "Black-Scholes" valuation methodology (which includes various assumptions).

The Onboarding Equity Grant is subject *to the approval of the Board of Directors of RSL* (the "Board") and *will* be subject *in all* respects *to the* terms and *conditions of the Roivant* Sciences *Ltd. 2021 Equity Incentive Plan* and *the applicable grant* documents *(which will control in the* event *of* any conflicts *with this offer letter),* as *further described* on *the following* pages.

You will be *eligible to receive additional annual equity* grants *in the future,* subject *to* an assessment, *at the Company* and *the* Board's sole *discretion, of your performance* as we// as *general* business *conditions at the Company.*

Benefits: Our benefits include medical, dental, vision, life and disability insurance, and a 40l(k) program with a company match. Rather than a fixed number of days for vacation, we offer a flexible time-off policy that empowers employees to take paid time-off as needed to recharge and be as productive as possible, after discussion with their manager - in turn, employees are held accountable for results, not face-time.

The next few pages cover additional terms of your offer and should be read in combination with the details above. I am also including a copy of Roivant's Core Principles, which are essential to how we operate. Don't hesitate to contact me with any questions. Otherwise, please confirm your acceptance by 02/10/2025.

We are very excited for you to join the team and look forward to driving Roivant's continued success together!

Best,

/s/ Eric Venker
Eric Venker
Chief Operating Officer, Roivant Sciences, Inc.

Agreed and Accepted:

By: /s/ Jennifer Humes Date: 2/7/2025
Jennifer Humes

More Terms of your Offer

Our offer is contingent on you signing a Non-Disclosure, Invention Assignment and Restrictive Covenant Agreement and a Mutual Arbitration Agreement, satisfactorily completing your background check, and submitting valid proof of your identity and your legal authorization to work in the United States. Your continued employment is subject to compliance with applicable company policies.

Target Annual Bonus: The target annual bonus is a discretionary component of your offer. The bonus is at the sole discretion of Roivant and Roivant's assessment of your performance and general business conditions. If your performance assessment is done for a period covering less than a full fiscal year, this bonus would be pro-rated for your period of employment. Roivant's fiscal year is Aprill to March 31. Your bonus is payable after the end of the fiscal year (March 3l51) and within thirty (30) days (by April 30th). You must be employed at Roivant at the time the bonus is paid to be eligible to receive the bonus.

Other Terms: Your salary may be reviewed annually. Your employment is classified as exempt from overtime and is on an at-will basis. You or Roivant may terminate your employment for any reason or no reason and at any time. If you choose to do so, Roivant requests that you resign providing thirty (30) days' notice.

Sign-on Bonus: The one-time sign-on bonus is payable, less all required tax withholdings and other applicable deductions, within thirty (30) days following your start date (the "Payment Date"). In the event that your employment with Roivant or any of its affiliates terminates for any reason, whether terminated by the Company or by you, at any time on or prior to the second anniversary of the Payment Date, you will be required to repay to the Company unless otherwise agreed by the Company in writing and in its sole discretion, 100% of the gross amount of the sign-on bonus. You will be required to repay the Company via personal check no later than ten (10) days following your termination date. Please note that you may be liable for any collection costs incurred by the Company should you not repay pursuant to the foregoing terms.

More Details on Your Equity Incentives
Roivant Sciences Ltd. Restricted Stock Units:

A restricted stock unit ("RSU") reflects a right to receive a specified number of common shares of Roivant Sciences Ltd. ("RSL"), subject to the satisfaction of certain vesting conditions.

Your grant of RSUs is subject to the approval of the Board of Directors of RSL and the terms and conditions of the Roivant Sciences Ltd. 2021 Equity Incentive Plan (the "Plan"), your Restricted Stock Unit Agreement (your "RSU Agreement"), and any other documents pursuant to which your RSUs are granted (collectively, your "RSU Grant Documents").

- **Number of RSUs:** The exact number of RSUs to be granted to you will be determined as of the grant date by dividing the aggregate estimated cash value set forth on the first page of this letter by the fair market value per common share of Roivant Sciences Ltd. as of the grant date, as determined by RSL and calculated by reference to the public trading price of RSL's common stock prior to the grant date (using either a spot or average trading price, as determined by RSL).

- **Grant Date:** It is anticipated that your RSUs will be granted on the 20th day of the month (or next business day if the 20th day is a weekend or holiday) commencing after your first day of work.

- **Vesting:** Your RSUs will be subject to a 4-year service-period vesting condition, with 25% vesting on the first anniversary of the vesting commencement date that will be set forth in the RSU Grant Documents, and the balance of the RSUs vesting in twelve (12) equal quarterly installments thereafter, in each case subject to your continued employment through the applicable vesting date. Importantly, your RSUs will not vest and become payable unless and until the applicable vesting condition is satisfied (if at all).

The foregoing summary is subject in all respects to, and qualified in its entirety by, the terms and conditions applicable to your RSUs as set forth in the RSU Grant Documents. In the event of any conflict between this summary and the terms and conditions of the RSU Grant Documents. the terms and conditions of the RSU Grant Documents will prevail. A copy of the Plan and form of RSU Agreement is available upon request.

The estimated aggregate value of your RSUs as of the grant date that will be used to determine the number of RSUs to be granted to you is provided solely for illustrative purposes, and is not a promise to pay any value upon the vesting or settlement of your RSUs, nor is it an indication of future value. The actual value of your RSUs on the grant date or settlement date may differ from the estimated value of your RSUs reflected in this letter.

Roivant Sciences Ltd. Stock Options:

A stock option ("Stock Option") is a right to buy a specified number of common shares of Roivant Sciences Ltd. ("RSL") at a fixed "exercise price," subject to the satisfaction of certain vesting conditions.

Your grant of Stock Options, is subject to the approval of the Board of Directors of RSL and the terms and conditions of the Amended and Restated Roivant Sciences Ltd. 2021 Equity Incentive Plan (the "Plan"), your Stock Option Grant Agreement (your "Option Grant Agreement"), and any other documents pursuant to which your Stock Options are granted (collectively, your "Option Grant Documents").

- **Number of Options:** The exact number Stock of Options to be granted to you will be determined as of the grant date by dividing the aggregate estimated cash value set forth on the first page of this letter by the most recent value of a single option of RSL, in effect as of the grant date, as determined by RSL calculated using a "Black-Scholes" valuation methodology (which includes various assumptions).

- **Exercise Price:** The exercise price for your Stock Options will be equal to the fair market value of RSL's common stock as of the grant date.

- **Grant Date:** It is anticipated that your Stock Options will be granted on the 20th day of the firth full calendar month following you start date (or next business day if the 20th day is a weekend or holiday) commencing after your first day of work.

- **Vesting/Exercise:** Your Stock Options will:

  i. be subject to a 4-year vesting period, with 25% vesting on the first anniversary of the vesting commencement date that will be set forth in the Option Grant Documents and the balance of the Stock Options vesting in thirty-six (36) equal monthly installments thereafter, in each case subject to your continued employment through the applicable vesting date, and

  ii. expire and cease to be exercisable on the ten (10) year anniversary of the grant date (or earlier in certain circumstances as may be described in the Option Grant Documents).

The foregoing summary is subject in all respects to and qualified in its entirety by, the terms and conditions applicable to your stock options as set forth in the Option Grant Documents. In the event of any conflict between this summary and the terms and conditions of the Option Grant Documents the terms and conditions of the Option Grant Documents will prevail. A copy of the Plan and form of Option Grant Agreement is available upon request.

The estimated aggregate value of your Stock Options on the grant date that will be used to determine the number of Stock Options you are granted is provided solely for illustrative purposes and is not a promise to pay any value upon granting, vesting or exercise of your Stock Options, nor is it an indication of future value. The Black Scholes value of your Stock Options on the grant date, vesting date, or exercise date, may differ from the estimated value of your Stock Options reflected in this letter.

Equity* awards *are* subject to restrictions on *transfer. We* cannot make *any* guarantee *as* to *the actual* current *or* future *value of RSL's equity, including your RSUs.

Exhibit 10.2

AMENDED AND RESTATED

EXECUTIVE EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (the "**Agreement**") is hereby entered into as of July 28, 2025, by and between Roivant Sciences, Inc., a Delaware corporation (the "**Company**"), and Eric Venker, an individual ("**Executive**") (hereinafter collectively referred to as the "**Parties**"). Reference is made to that certain Employment Agreement entered into by and between Executive and IMVT Corporation ("**IMVT**"), an affiliate of the Company, dated as of July 28, 2025 (as amended from time to time, the "**IMVT Employment Agreement**").

RECITALS

WHEREAS, the Company and Executive are party to that certain Executive Employment Agreement, dated as of May 14, 2021 (the "**Existing Agreement**"), which sets forth the terms and conditions of Executive's employment with the Company;

WHEREAS, effective as of April 21, 2025 (the "**Effective Date**"), Executive commenced employment with IMVT as the Chief Executive Officer of IMVT;

WHEREAS, in addition to serving as the Chief Executive Officer of IMVT, the Company desires to continue the employment of Executive on the terms and conditions set forth herein, and Executive desires to accept the terms and conditions of continued employment with the Company on the terms and conditions set forth herein; and

WHEREAS, as of the date hereof, this Agreement shall supersede and replace the Existing Agreement in its entirety, and the Existing Agreement shall be of no further force or effect.

NOW, THEREFORE, in consideration of the respective agreements of the Parties contained herein, it is agreed as follows:

1. *Employment Period; "At-Will" Employment*.

(a) The term of Executive's employment under this Agreement shall commence on the Effective Date and shall continue until Executive's employment with the Company is terminated in accordance with Section 4 (the "**Employment Period**"). For the avoidance of doubt, the execution of this Agreement and replacement of the Existing Agreement shall in no event be deemed to result in an interruption in Executive's continuous service to the Company for the purposes of any equity incentive awards previously granted to Executive or for any other reason.

(b) Executive's employment with the Company hereunder is "at-will," such that each of Executive and the Company has the right to terminate Executive's employment hereunder at any time and for any reason, with or without advance notice, subject to Section 4 hereof.

2. *Position and Duties; Location*.

(a) During the Employment Period, Executive shall be employed as the Company's President and Immunovant CEO (the "**Role**"). Executive shall report directly to the Chief Executive Officer of the Company. Executive shall have such duties and responsibilities as are commensurate with Executive's position, as may be assigned to Executive from time to time by the Chief Executive Officer of the Company. It is understood and agreed that Executive's duties may include providing services to or for the benefit of the Company's affiliates, including, but not limited to, Roivant Sciences Ltd. ("**Parent**"), IMVT and certain Private UK Vants (as defined below); *provided* that Executive agrees that Executive will not provide any services from within the United States for Parent, the Private UK Vants or any other affiliate of Parent that is organized in a jurisdiction outside the United States.

Executive will not become an employee of Parent, and Executive's activities in respect of services to Parent shall be strictly ministerial and shall not involve conducting any of Parent's business activities from within the United States, including day-to-day management or other operational activities of Parent.

(b) The Company acknowledges that, as of the Effective Date, Executive is co-employed by the Company and IMVT (with respect to IMVT, pursuant to the terms of the IMVT Employment Agreement). During the Employment Period, Executive shall not engage in any other business, profession or occupation, whether paid or unpaid, that would conflict with the performance of Executive's services hereunder and under the IMVT Employment Agreement, either directly or indirectly. During the Employment Period, Executive shall not be permitted to serve on the board of directors of any entity or organization without the prior written consent of the General Counsel of the Company (or their designee) (except with respect to the Company and its affiliates); *provided* that Executive may serve on the board of directors of charitable organizations without such prior written consent so long as such board service does not conflict or interfere with the performance of the Role. Notwithstanding anything to the contrary herein, Executive shall not engage in any activities that constitute a conflict of interest with the interests of the Company or its direct or indirect subsidiaries and affiliates (together with Parent, collectively, the "**Company Group**").

(c) During the Employment Period, Executive's principal place of employment shall be the Company's offices located in New York, New York; *provided* that Executive acknowledges that Executive's duties and responsibilities shall require Executive to periodically travel on business to the extent necessary to fully perform Executive's duties and responsibilities hereunder.

(d) Executive shall be subject to and shall abide by each of the Company Group's personnel policies applicable to Executive, including but not limited to any code of conduct, any insider trading policy, any policy restricting pledging and hedging investments in equity securities of any member of the Company Group, any share ownership policy or commitment and any policy regarding the recoupment of compensation that the Company Group may adopt from time to time or that may otherwise be required under any applicable law or applicable listing rules. This Section 2(d) shall survive the termination of the Employment Period.

3. *Compensation and Benefits*. The following sets forth the terms of the compensation and benefits to be provided to Executive during the Employment Period in respect of Executive's services under this Agreement.

(a) During the Employment Period, Executive shall receive an annual base salary of $75,000 (as adjusted from time to time, "**Base Salary**"). The Base Salary shall be payable in accordance with the Company's regular payroll practices as in effect from time to time commencing on the first of the month following the execution of this Agreement. During the Employment Period, the Base Salary will be reviewed annually by, and is subject to adjustment at the discretion of, the compensation committee of the Board of Directors of Parent (the "**Committee**"); *provided* that (i) the Base Salary shall be reduced by the aggregate annual amounts payable to Executive pursuant to Section 3(h) and (ii) in the event that Executive's employment with IMVT terminates other than for Cause and Executive continues to be employed by the Company in the Role (or a substantially similar role) on a full-time basis thereafter (without interruption), the Base Salary shall be increased to Executive's base salary payable by the Company as in effect immediately prior to the Effective Date (as may be adjusted by the Committee in good faith at such time and from time to time). For the avoidance of doubt, in no event shall the annual amounts payable to Executive under this Section 3(a) and Section 3(h) exceed Executive's Base Salary then in effect for the applicable fiscal year, subject to the adjustment at the discretion of the Committee.

(b) For any fiscal year of the Company during the Employment Period (or any applicable portion thereof) in which Executive served in the Role and was not co-employed by IMVT, Executive shall be eligible to receive a discretionary annual performance bonus (the "**Annual Bonus**"). For any such fiscal year, Executive's target Annual Bonus shall be equal to 75% of Executive's Base Salary in effect for the applicable fiscal year (without giving effect to any reductions in such Base Salary for Vant Board Fees). The actual amount of the Annual Bonus for any fiscal year, if any, shall be subject to an assessment, in the sole discretion of the Committee, of Executive's performance as well as business conditions at the Company, and shall be pro-rated for the number of days Executive served in the Role without co-employment by IMVT. By way of example and without limiting the foregoing, for the fiscal year ended March 31, 2026, during which Executive served in the Role and was not co-employed by IMVT for the period from and including April 1, 2025 to but not including April 21, 2025 (the "**Stub Period**"), Executive would be eligible to receive an Annual Bonus covering the Stub Period based on actual achievement of the performance goals for the full fiscal year, and prorated based on the number of days served in the Role during the Stub Period. For any fiscal year of the Company in which Executive was co-employed by IMVT for the entirety of such fiscal year and was eligible to receive an annual cash bonus from IMVT, Executive shall not be eligible to earn an annual discretionary cash bonus from the Company in respect of such fiscal year. Executive's Annual Bonus (if any) for any fiscal year shall be paid no later than thirty (30) days following the end of the Company's fiscal year. In order to receive an Annual Bonus for any fiscal year, Executive must remain employed by the Company through the applicable payment date of such Annual Bonus.

(c) Subject to the terms of the Roivant Sciences Ltd. 2021 Equity Incentive Plan (as amended or restated from time to time and including any successor plan thereto, the "**Parent Equity Plan**") and approval of the grant by the Committee as soon as reasonably practicable following the date hereof, Executive will be granted an award of restricted stock units with an aggregate grant date fair value equal to approximately $2,250,000 (the "**Parent RSU Award**") pursuant to the Parent Equity Plan, with the number of Parent common shares subject to the Parent RSU Award determined based on the 30-day trailing average price of Parent's common shares on the Nasdaq Global Select Market as of the grant date and rounding down to the nearest whole share. The Parent RSU Award will vest over a period of four years, with twenty-five percent (25%) of the Parent RSU Award vesting on May 20, 2026 (the "First Vesting Date") and the balance of the Parent RSU Award vesting in a series of twelve (12) successive equal quarterly installments following the First Vesting Date, provided Executive is employed by the Company or IMVT on each such vesting date and subject to the terms of the Parent Equity Plan and the applicable award agreement thereunder. In all cases, the Parent RSU Award will be subject to the terms and conditions contained in the Parent Equity Plan and the applicable award agreement between Executive and Parent, which shall control in the event of any conflict herewith.

(d) During the Employment Period, Executive may be eligible to receive discretionary periodic or annual equity incentive grants under the Parent Equity Plan, based upon Executive's performance as well as business conditions at the Company, as determined in the sole discretion of the Committee.

(e) During the Employment Period, Executive shall be entitled to participate in the employee benefit plans and programs (including any medical, dental, vision, life and disability insurance benefit plans and 401(k) plan) made available by the Company to similarly situated full-time employees of the Company from time to time, subject to and in accordance with the terms of such plans or programs (including with respect to eligibility requirements and enrollment criteria) in effect from time to time, it being understood that Executive shall be eligible to participate in the benefits and insurance plans and other arrangements at either (but not both) of IMVT and the Company. The Company reserves the right to change or rescind its benefit plans and programs and alter employee contribution levels from time to time at its discretion.

(f) During the Employment Period, Executive shall be entitled to vacation and sick leave in accordance with, and subject to the terms of, the Company's vacation and sick leave policies and programs, as may be amended from time to time. For the avoidance of doubt, any vacation or sick leave taken with respect to Executive's role with IMVT shall count as vacation and sick leave under the terms of the Company's vacation and sick leave policies and programs.

(g) The Company shall reimburse Executive for reasonable travel and other business-related expenses incurred by Executive in the fulfillment of the Role; *provided*, in each case, that such expenses are incurred and accounted for in accordance with the policies and procedures established by the Company from time to time. Any such reimbursement of expenses shall be made by the Company as soon as practicable following receipt of supporting documentation reasonably satisfactory to the Company (but in any event not later than the close of Executive's taxable year following the taxable year in which the expense is incurred).

(h) During the Employment Period, Executive shall be entitled to receive a cash payment of $3,125 per fiscal quarter in the form of board fees (or such other amount as may be determined by Parent) in respect of each UK private company affiliate of Parent (each, a "**Private UK Vant**") for which Executive serves as a member of the board of directors (such fees payable from all Private UK Vants, in the aggregate, the "**Vant Board Fees**"). The Company shall use reasonable best efforts to cause the applicable Private UK Vant to pay the applicable Vant Board Fees to Executive in quarterly installments in arrears while Executive is serving on such Private UK Vant's board of directors (subject to Section 4(b)).

4. *Termination of Employment*.

(a) The Employment Period and Executive's employment under this Agreement shall be terminated in accordance with this Section 4: (i) immediately upon Executive's death or Disability (as defined below); (ii) by the Company at any time for Cause (as defined below) or, upon at least thirty (30) days' prior written notice, without Cause; (iii) voluntarily by Executive without Good Reason (as defined below) upon at least ninety (90) days' prior written notice (*provided* that, at any time after Executive has provided such written notice to the Company, the Company may, in its sole discretion, elect to terminate Executive's employment hereunder at any time prior to the end of such 90-day period, in which case, and notwithstanding anything to the contrary in this Agreement or otherwise, Executive shall thereupon only be entitled to receive the Accrued Obligations (as defined below) and such termination of employment will not constitute a termination of employment without Cause or otherwise entitle Executive to any Severance Benefits (as defined below)); or (iv) by Executive for Good Reason. The effective date of the termination of Executive's employment hereunder is referred to herein as the "**Termination Date**." Notwithstanding anything to the contrary herein, in the event Executive's employment with IMVT is terminated by IMVT for Cause (as defined under the IMVT Employment Agreement), such termination of employment with IMVT shall constitute Cause for purposes of this Agreement and the Company shall thereupon have the right to terminate Executive's employment with the Company hereunder for Cause.

(b) In the event of a termination of Executive's employment for any reason, Executive (or Executive's beneficiaries, as the case may be) shall be entitled to receive (i) Executive's accrued but unpaid then-current Base Salary through the Termination Date, (ii) reimbursement for any unreimbursed business expenses that are reimbursable in accordance with Section 3(g), subject to the Company's requirements with respect to reporting and documentation of such expenses, (iii) any unpaid Vant Board Fees for the applicable fiscal quarter during which the Termination Date occurs (prorated for the number of days during such fiscal quarter elapsed prior to the Termination Date) and (iv) any other vested amount or benefit, if any, that is expressly provided for pursuant to the terms of any employee benefit plan or program in which Executive participates (the amounts described in clauses (i) through (iv), collectively, the "**Accrued Obligations**").

(c) In addition to the Accrued Obligations, subject to the terms of Section 4(d), in the event (1) the Company terminates Executive's employment without Cause (other than due to death or Disability) or (2) Executive resigns for Good Reason, Executive shall be entitled to receive (A) continued payment of Executive's then-current Base Salary (without giving effect to any reductions in such Base Salary for Vant Board Fees) for a period of twelve (12) months following the Termination Date, payable in accordance with the Company's customary payroll practices; (B) an amount equal to Executive's target Annual Bonus, if any, payable in equal monthly installments over the twelve (12) month period following the Termination Date in accordance with the Company's customary payroll practices; and (C) to the extent that Executive is already enrolled in the Company's group health and dental plans as of immediately prior to the Termination Date, monthly subsidy of the COBRA premiums for continued group health and dental plan coverage in which Executive is enrolled as of immediately prior to the Termination Date, less active employee rates (which will be payable by Executive), for a period of twelve (12) months following the Termination Date or, if earlier, until the date Executive becomes eligible to be covered under a subsequent employer's group health insurance plan (the amounts described in clauses (A) through (C), collectively, the "**Severance Benefits**"); *provided that*, notwithstanding the foregoing, in the event that each of Executive and IMVT desires that Executive continue in his capacity as Chief Executive Officer of IMVT (or in another position with IMVT to be mutually agreed between Executive and IMVT) following Executive's termination of employment from the Company pursuant to this Section 4(c), Executive shall not have any rights or entitlements to the Severance Benefits or any other severance or other payments under this Agreement, except for the Accrued Obligations, and Executive's eligibility for any severance in connection with Executive's subsequent termination of employment with IMVT shall be governed by the terms and conditions of the IMVT Employment Agreement. Executive agrees to provide the Company with written notice of Executive's eligibility to be covered under a subsequent employer's group health insurance plan no later than five (5) business days after Executive becomes eligible for such coverage. For the sake of clarity, the Severance Benefits will only be paid under this Agreement to the extent that Executive's employment with the Company terminates in the circumstances described in this Section 4(c) and Executive does not continue employment with IMVT thereafter.

(d) Notwithstanding anything to the contrary herein, the Severance Benefits shall be provided to Executive only if (A) Executive has executed and delivered to the Company a waiver and general release of claims, in a form to be provided promptly by the Company following the Termination Date (the "**Release**"), which such Release must be executed, delivered and be irrevocable within sixty (60) days after the Termination Date, (B) Executive has not revoked or breached the provisions of such Release and (C) Executive has not violated the terms of the NDIA (as defined below). Notwithstanding anything to the contrary herein, any payment of the Severance Benefits under Section 4(c)(A) or 4(c)(B) that is scheduled to occur during the first sixty (60) days following the Termination Date shall not be paid until the first regularly scheduled payroll date following such period and shall include payment of any amount that was otherwise scheduled to be paid prior thereto. If the period during which Executive may execute or revoke the Release spans two taxable years of Executive, the Severance Benefits shall in all events be paid to Executive in the second such taxable year, and any Severance Benefits that otherwise would have been payable during the first taxable year shall be paid in a lump sum in the first calendar month of the second taxable year.

(e) Executive acknowledges and agrees that the Company has no obligation to pay Executive any severance, except as expressly provided herein or as may otherwise be approved by the Company, and only to the extent Executive complies with the express contractual conditions hereof.

(f) For purposes of this Agreement, the following terms shall have the following meanings:

(i) "**Cause**" shall mean Executive's: (A) conviction of, or plea of guilty or no contest to, any (x) felony or (y) any other crime involving moral turpitude or dishonesty; (B) participation in fraud, embezzlement, misappropriation or theft against any member of the Company Group; (C) material breach of this Agreement or any other agreement between Executive and any member of the Company Group that has not been cured (if curable) within thirty (30) days after receiving written notice of such breach; (D) engagement in any conduct or act of gross negligence that causes, or is reasonably likely to cause, material damage to any member of the Company Group monetarily or otherwise (including, with respect to the reputation, business or business relationships of any member of the Company Group); (E) material failure to comply with the code of conduct or other material policies of any member of the Company Group; (F) violation of any law, rule or regulation relating in any way to the business or activities of the Company Group, or any other law, rule or regulation that results in Executive's arrest, censure or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities; or (G) willful failure to substantially perform the Role (other than as a result of Disability) that has not been cured (if curable) within thirty (30) days after receiving written notice from the Company.

(ii) "**Disability**" shall have the meaning assigned to such term in the Parent Equity Plan.

(iii) "**Good Reason**" shall mean the occurrence of any of the following events without Executive's consent: (A) a material reduction in Executive's Base Salary (*provided*, *however*, that if such reduction occurs in connection with a Company-wide decrease in the compensation of similarly situated employees of the Company, such reduction shall not constitute Good Reason if it is a reduction of a proportionally like percentage affecting all such similarly situated employees not to exceed ten percent (10%)); (B) a material reduction of Executive's authority, duties or responsibilities, as compared to Executive's authority, duties or responsibilities immediately prior to such reduction; or (C) a relocation of Executive to a primary office location more than twenty five (25) miles from Executive's primary company office location as of the Effective Date (*provided* that Executive being permitted to work remotely shall not constitute Good Reason); *provided* that, in each case Executive (1) gives the Company written notice of Executive's intent to terminate employment for Good Reason within thirty (30) days following the first occurrence of the conditions that Executive believes constitute Good Reason, (2) the Company fails to remedy such conditions within thirty (30) days following receipt of the written notice from Executive and (3) Executive voluntarily terminates employment within thirty (30) days following the expiration of such cure period.

5. *Nondisclosure and Restrictive Covenants*. Executive agrees to be bound by the terms and conditions of the Employee Non-Disclosure, Invention Assignment and Restrictive Covenant Agreement (the "**NDIA**") between the Company and Executive, a copy of which is attached as Exhibit A hereto. The terms of the NDIA are incorporated herein by reference and deemed to be a part of this Agreement. This Section 5 (and the NDIA) shall survive the termination of the Employment Period.

6. *Executive's Cooperation*. During the Employment Period and thereafter, Executive shall cooperate in good faith with the Company in any internal investigation or administrative, regulatory or judicial proceeding as reasonably requested by the Company (including, without limitation, Executive being available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process, volunteering to the Company all pertinent information and turning over to the Company all relevant documents which are or may come into Executive's possession, all at times and on schedules that are reasonably consistent with Executive's other permitted activities and commitments). The Company will reimburse Executive for any reasonable, out-of-pocket travel, lodging and meal expenses incurred in connection with Executive's performance of obligations pursuant to this Section 6 for which Executive has obtained prior written approval from the Company. This Section 6 shall survive the termination of the Employment Period.

7. *Executive's Representations*. Executive hereby represents and warrants to the Company that (i) Executive's execution and delivery of this Agreement and the performance by Executive of the Role shall not constitute a breach of, or otherwise contravene, the terms of any employment, restrictive covenant or other agreement or policy to which Executive is a party or otherwise bound, (ii) Executive is not subject to any obligation or restriction that would affect Executive's ability to devote Executive's full time and attention to the Role and (iii) Executive has not been debarred, or received notice of any action or threat with respect to debarment, under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the U.S. or in any other country where the Company intends to develop its activities.

8. *Assignment; Binding Effect*. This Agreement and any and all rights, duties, obligations or interests hereunder shall not be assignable or delegable by Executive. This Agreement and all of the Company's rights and obligations hereunder shall not be assignable by the Company, except as incident to a reorganization, merger, amalgamation or consolidation, or transfer of all or substantially all of the Company's assets, or to an affiliate of the Company. This Agreement shall be binding upon, and inure to the benefit of, the Parties, any successors to or assigns of the Company and Executive's heirs and the personal representatives of Executive's estate.

9. *Amendment; Waiver.* This Agreement may not be modified, amended or waived in any manner, except by an instrument in writing signed by both Parties. The waiver by either Party of compliance with any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by such Party of a provision of this Agreement.

10. *Survival*. To the extent contemplated by this Agreement, the respective rights and obligations of the Parties shall survive and continue in full force in accordance with their terms notwithstanding the termination of the Employment Period.

11. *Notices*. For the purposes of this Agreement, notices and all other communications provided for in the Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or sent by certified mail, return receipt requested, postage prepaid, addressed to the respective addresses last given by each Party to each other Party; *provided* that all notices to the Company shall be directed to the attention of the General Counsel of the Company. All notices and communications shall be deemed to have been received on the date of delivery thereof or on the third business day after the mailing thereof, except that notice of change of address shall be effective only upon receipt.

12. *Withholding*. Any payments made or benefits provided to Executive under this Agreement shall be reduced by any applicable withholding taxes or other amounts required to be withheld by law or contract. The Company, in its sole and absolute discretion, shall make all determinations as to whether it is obligated to withhold any taxes hereunder and the amount hereof.

13. *Section 409A and Section 457A(a)*. It is intended that the provisions of this Agreement comply with or are exempt from Section 409A and Section 457A of the Internal Revenue Code of 1986, as amended (the "**Code**") (together with the regulations and other interpretive guidance issued thereunder, "**Section 409A**" and "**Section 457A**", respectively), and all provisions of this Agreement will be construed and interpreted in a manner consistent with such intent. In no event shall the Company or any of its affiliates be liable for any additional tax, interest or penalty that may be imposed on Executive by Section 409A or Section 457A. For purposes of Section 409A, each right to a payment hereunder will be deemed a "separate payment" within the meaning of Treas. Reg. Section 1.409A-2(b)(iii). With respect to the timing of payments of any deferred compensation payable upon a termination of employment hereunder, references in this Agreement to "termination of employment" (and substantially similar phrases) mean "separation from service" within the meaning of Section 409A. For the avoidance of doubt, it is intended that any expense reimbursement made to Executive hereunder is exempt from Section 409A; however, if any expense reimbursement hereunder is determined to be deferred compensation within the meaning of Section 409A, then (i) the amount of the expense reimbursement during one taxable year will not affect the amount of the expense reimbursement during any other taxable year, (ii) the expense reimbursement will be made on or before the last day of the year following the year in which the expense was incurred, and (iii) the right to expense reimbursement hereunder will not be subject to liquidation or exchange for another benefit. To the extent that Executive is a "specified employee" within the meaning of Section 409A as of the date of Executive's separation from service (as determined by the Company), no amounts payable under this Agreement that constitute "deferred compensation" within the meaning of Section 409A that are payable on account of Executive's separation from service shall be paid to Executive until the expiration of the six (6)-month period measured from the date of such separation from service (or, if earlier, the date of Executive's death following such separation from service). Upon the first business day following the expiration of such delay period, all such amounts deferred pursuant to the preceding sentence will be paid to Executive (without interest).

14. *Section 280G*. If Executive would be entitled to payments or benefits under this Agreement or under any other plan, program, agreement or arrangement that would constitute "parachute payments" as defined in Section 280G of the Code and could result in any such payment or benefit being subject to an excise tax under Section 4999 of the Code, the present value of Executive's payments and benefits will be reduced by the minimum amount necessary such that the aggregate present value of such payments and benefits do not trigger the excise tax; *provided*, *however*, no such reductions shall be given effect if Executive would be entitled to greater payments and benefits on an after-tax basis (taking into account the excise tax imposed pursuant to Section 4999 of the Code, any tax imposed by any comparable provision of state law, and any applicable federal, state and local income and employment taxes) than if such reductions were to be implemented. If payments or benefits are to be reduced, any such reduction in payments and/or benefits shall be made in accordance with Section 409A and shall occur in the manner that results in the greatest economic benefit to Executive as determined by the Company's independent accountants. All determinations in applying the foregoing provisions for purposes of the "golden parachute" rules under Sections 280G and 4999 of the Code will be made by the Company's independent accountants and shall be final and binding on the parties.

15. *Governing Law*. This Agreement (together with any and all modifications, extensions and amendments) shall be governed by and construed and enforced in accordance with the laws of the State of New York applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict or choice of law principles thereof.

16. *Severability*. Each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any action in any other jurisdiction, but this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

17. *Arbitration*. If any legally actionable dispute arises under this Agreement, the IMVT Employment Agreement or otherwise which cannot be resolved by mutual discussion between the Parties, then the Company and Executive each agrees to resolve that dispute by binding arbitration pursuant to the terms and conditions of the Mutual Agreement to Arbitrate Claims (the "**Arbitration Agreement**") previously entered into between the Company and Executive, a copy of which is attached as Exhibit B hereto. The terms of the Arbitration Agreement are incorporated herein by reference and deemed to be a part of this Agreement. This Section 17 (and the Arbitration Agreement) shall survive the termination of the Employment Period.

18. *Waiver of Jury* Trial. EACH PARTY EXPRESSLY WAIVES THE RIGHT TO TRIAL BY JURY IN ANY LAWSUIT OR PROCEEDING RELATING TO OR ARISING IN ANY WAY FROM THIS AGREEMENT OR THE MATTERS CONTEMPLATED HEREBY.

19. *Entire Agreement*. This Agreement, along with the NDIA, the IMVT Employment Agreement, constitutes the entire agreement between the Parties and supersedes all prior agreements, if any, understandings and arrangements, oral or written, between the Parties with respect to the subject matter hereof, including without limitation, the Existing Agreement, but excluding the Arbitration Agreement.

20. *Captions and Headings*. The descriptive captions and headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement.

21. *Counterparts*. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement. Signatures transmitted via facsimile or .pdf will be deemed the equivalent of originals.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written, to be effective as of the date first written above.

ROIVANT SCIENCES, INC.

By: /s/ Matthew Gline
Name: Matthew Gline
Title: CEO

EXECUTIVE

By: /s/ Eric Venker
Name: Eric Venker
Title: President and Immunovant CEO

[*Signature Page to Amended and Restated Employment Agreement*]

Exhibit A

Employee Non-Disclosure, Invention Assignment and Restrictive Covenant Agreement

[*Attached*]

Exhibit B

Mutual Agreement to Arbitrate Claims

[*Attached*]

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: August 11, 2025

/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: August 11, 2025

/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 June 30, 2025, 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: August 11, 2025

/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 June 30, 2025, 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: August 11, 2025

/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.

Exhibit 10.3

EMPLOYMENT AGREEMENT

This Employment Agreement (this "**Agreement**") is entered into as of July 28, 2025, by and between Eric Venker (the "**Executive**") and IMVT Corporation (the "**Company**"). Reference is made to that certain Amended and Restated Executive Employment Agreement entered into by and between the Executive and Roivant Sciences, Inc. ("**RSI**"), an affiliate of the Company, dated as of July 28, 2025 (as amended from time to time, the "**RSI Employment Agreement**").

RECITALS

A. The Company desires the association and services of the Executive and the Executive's skills, abilities, background and knowledge, and is willing to engage the Executive's services on the terms and conditions set forth in this Agreement.

B. The Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement.

C. This Agreement supersedes any and all prior and contemporaneous oral or written employment agreements or arrangements between the Executive and the Company or any predecessor thereof.

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. **EMPLOYMENT BY THE COMPANY**.

1.1. **Position; Duties**. Subject to the terms and conditions of this Agreement, the Executive shall hold the position of Chief Executive Officer of the Company and of Immunovant, Inc. (the "**Parent**"). In this position, the Executive will have the duties and authorities normally associated with a Chief Executive Officer of a public company. The Executive will report to the board of directors of the Parent (the "**Parent Board**").

1.2. **Co-Employment Acknowledgment**. The Company acknowledges that the Executive will continue to be employed by RSI with the title "President and Immunovant CEO" and will continue to serve as a director of Parent and certain other affiliates of the Parent.

1.3. **Location of Employment**. The Executive's principal place of employment shall be New York, New York. The Executive understands that the Executive's duties also will require periodic business travel.

1.4. **Start Date**. The Executive's employment with the Company commenced on April 21, 2025 (the "**Start Date**").

1.5. **Exclusive Employment; Agreement Not to Compete**. Except with the prior written consent of the Parent Board, the Executive will not, during the Executive's employment with the Company, undertake or engage in any other employment, occupation or business enterprise, and shall not be permitted to serve on the board of directors of any entity or organization (except with respect to RSI and its affiliates or for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, or (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties).

During the Executive's employment, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business, or prospects, financial or otherwise, or in any company, person, or entity that is, directly or indirectly, in competition with the business of the Company. Ownership by the Executive in professionally managed funds over which the Executive does not have control or discretion in investment decisions, or, an investment of less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed on a national securities exchange or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute a breach of this Section. Executive shall be subject to and shall abide by each of the Company's and Parent's personnel policies applicable to Executive, including but not limited to any code of conduct, any insider trading policy, any policy restricting pledging and hedging investments in equity securities of any member of the Company or its direct or indirect subsidiaries and affiliates (together with Parent, collectively, the "**Company Group**"), any share ownership policy or commitment and any policy regarding the recoupment of compensation that the Company Group may adopt from time to time or that may otherwise be required under any applicable law or applicable listing rules.

2. **COMPENSATION AND BENEFITS**.

2.1. **Salary**. The Company shall pay the Executive a base salary at the annualized rate of $672,000 (the "**Base Salary**"), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company's normal payroll practices, commencing on the first of the month following the execution of this Agreement. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be adjusted from time to time in the discretion of the Parent Board.

2.2. **Annual Performance Bonus**. Each fiscal year, the Executive will be eligible to earn an annual discretionary cash bonus (the "**Annual Performance Bonus**") with a target bonus opportunity equal to 72.25% of the Executive's Base Salary. The actual amount of the Annual Performance Bonus shall be subject to an assessment, in the sole discretion of the Parent Board (and/or an applicable committee thereof) of the Executive's individual performance and overall Company performance. In order to earn and receive the Annual Performance Bonus, the Executive must remain employed by the Company through and including the date on which the Annual Performance Bonus is paid. The Annual Performance Bonus, if any, will be paid no later than thirty (30) days following the end of the Company's fiscal year (March 31), or by April 30, subject to Executive's continued employment through the payment date. The Annual Performance Bonus payable, if any, shall be prorated for the initial year of employment (on the basis of a three hundred sixty-five (365)-day year) and shall be prorated if the Company's review or assessment of the Executive's performance covers a period that is less than a full fiscal year.

2.3. **Equity Incentive Grants**.

(a) Subject to the terms of Parent's 2019 Equity Incentive Plan (as may be amended from time to time, the "**Plan**") and approval of the grant by the Parent Board, the Executive will be granted an award of options to purchase 1,300,000 shares of common stock of the Parent (the "**Unit Option Award**"). The Unit Option Award will be granted on or about July 28, 2025, with an exercise price equal to the fair market value of Parent's common stock on such date of grant, as set forth in the Plan. The Unit Option Award will vest over a period of four years, with twenty-five percent (25%) of the Unit Option Award vesting on the one-year anniversary of the Start Date and the balance of the Unit Option Award vesting in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Start Date, provided Executive is employed by the Company on each vesting date, except as otherwise set forth herein.

(b) Subject to the terms of the Plan and approval of the grant by the Parent Board, the Executive will be granted an award of options to purchase a number of shares common stock of the Parent (the "**Dollar Option Award**" and, together with the Unit Option Award, the "**Option Awards**") determined by dividing $2,250,000 by the 30-day trailing average price of the Company's common stock on the Nasdaq Global Select Market as of the date of grant and rounding down to the nearest whole share. The Dollar Option Award will be granted on or about July 28, 2025, with an exercise price equal to the fair market value of Parent's common stock on such date of grant, as set forth in the Plan. The Dollar Option Award will vest over a period of four years, with twenty-five percent (25%) of the Dollar Option Award vesting on the one-year anniversary of the Start Date and the balance of the Dollar Option Award vesting in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Start Date, provided Executive is employed by the Company on each vesting date, except as otherwise set forth herein.

(c) If a Change in Control (as defined in the Plan) occurs during the term of Executive's employment with the Company, all then-outstanding and unvested Option Awards shall immediately vest in full and become exercisable upon such Change in Control (the "**Equity Acceleration Benefit**").

(d) Notwithstanding anything to the contrary herein, following each vesting event described in the this Section 2.3, the shares of common stock underlying such portion of the Unit Option Award will be subject to a further two (2) year holding period starting from the applicable vesting event before the shares of common stock underlying such portion of the Unit Option Award may be sold, unless the Executive acquires the prior written consent of the Parent Board (e.g., the shares of common stock underlying the 25% of the Unit Option Award that vests on the one-year anniversary of the Start Date must be held until the three-year anniversary of the Start Date before such shares may be sold), provided that Executive shall be permitted to sell such shares pursuant to any sell-to-cover transaction or dispose shares withheld to satisfy any applicable tax withholding obligations due in respect of the exercise of the Option Awards. In all cases, the Option Awards will be subject to the terms and conditions contained in the Plan and the applicable equity incentive agreement issued in connection with the grants, which will incorporate the terms set forth in this Section (the "**Option Equity Incentive Agreements**") between the Executive and the Parent. In the event of a conflict between the terms of this Agreement and the terms of the Option Equity Incentive Agreements, except in connection with the vesting schedule and acceleration rights set forth herein, the terms of the Option Equity Incentive Agreements shall prevail.

(e) Subject to the terms of the Plan and approval of the grant by the Parent Board, the Executive will be granted an award of 1,475,000 capped value appreciation rights ("**CVARs**") of the Parent on or about July 28, 2025. The terms of the CVARs will be set out in CVAR award grant notice, to be entered into by and between the Parent and the Executive.

Thereafter, during the term of the Executive's employment, the Executive may be eligible to receive additional discretionary annual equity incentive grants in amounts and on terms and conditions determined by the Parent Board in its sole discretion.

2.4. **Benefits and Insurance**. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company executives (including, but not limited to, being named as an officer for purposes of the Company's Directors & Officers insurance policy), it being understood that the Executive shall not participate in the same or similar health benefits and savings or spending accounts at both RSI and the Company simultaneously. The Company reserves the right in its sole discretion to modify, add or eliminate benefits at any time. All benefits shall be subject to the terms and conditions of the applicable plan documents, which may be amended or terminated at any time. The Executive shall be entitled to vacation each year, in addition to sick leave and observed holidays in accordance with the policies and practices of the Company. Vacation may be taken at such times and intervals as the Executive shall determine, subject to the business needs of the Company.

2.5. **Expense Reimbursements**. The Company will reimburse the Executive for all reasonable and documented business expenses that the Executive incurs in conducting the Executive's duties hereunder, pursuant to the Company's usual expense reimbursement policies.

3. **AT-WILL EMPLOYMENT**.

The Executive's employment relationship with the Company is, and shall at all times remain, at-will. This means that either the Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without Cause (as defined below) or advance notice, subject to the payment obligations set forth in Section 5.4.

4. **PROPRIETARY INFORMATION OBLIGATIONS; COOPERATION**.

4.1. **NDIA.** As a condition of employment, the Executive agrees to execute and abide by the Company's Employee Non-Disclosure, Invention Assignment and Restrictive Covenant Agreement ("**NDIA**").

4.2. **Cooperation**. During the Executive's employment with the Company and thereafter, Executive shall cooperate in good faith with the Company in any internal investigation or any administrative, regulatory or judicial proceeding as reasonably requested by the Company (including, without limitation, Executive being available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process, volunteering to the Company all pertinent information and turning over to the Company all relevant documents which are or may come into Executive's possession, all at times and on schedules that are reasonably consistent with Executive's other permitted activities and commitments). The Company will reimburse Executive for any reasonable, out-of-pocket travel, lodging and meal expenses incurred in connection with Executive's performance of obligations pursuant to this Section 4.2 for which Executive has obtained prior written approval from the Company.

5. **TERMINATION OF EMPLOYMENT.**

5.1. **Termination Generally**. Upon termination of Executive's employment for any reason, the Company shall pay the Executive any earned but unpaid Base Salary, unused vacation accrued (if applicable) and any other vested amount or benefit, if any, that is expressly provided for pursuant to the terms of any employee benefit plan or program in which Executive participates (collectively, the "**Accrued Obligations**") through the date of termination, at the rates then in effect, less standard deductions and withholdings.

5.2. **Termination of IMVT Employment for Cause**. In the event the Executive's employment with the Company is terminated for Cause (as defined below), the Executive shall be deemed to be immediately terminated from all other positions with the Parent and its subsidiaries, including service on the Parent Board. The Company shall thereafter have no further obligations to the Executive, except for the Accrued Obligations or as otherwise required by law.

5.3. **Termination of RSI Employment for Cause**. In the event the Executive's employment with RSI is terminated for Cause (as such term is defined in the RSI Employment Agreement), Executive shall be deemed to be immediately terminated from all positions held at the Parent and its subsidiaries, including service on the Parent Board, for Cause under this Agreement (and the terms of Section 5.2 shall thereupon apply).

5.4. **Termination of IMVT Employment by the Company without Cause or Resignation by the Executive for Good Reason**.

(a) In the event the Company terminates the Executive's employment without Cause or Executive resigns for Good Reason (as defined below), the Executive shall be entitled to receive, in addition to the Accrued Obligations: (i) continued payment of the Executive's then-current Base Salary for a period of twelve (12) months following the termination date, payable in accordance with the Company's customary payroll practices; (ii) an amount equal to the Executive's target Annual Performance Bonus, payable in equal monthly installments over the twelve (12) month period following the termination date in accordance with the Company's customary payroll practices; and (iii) to the extent that the Executive is enrolled in the Company's group health and welfare benefit plans as of immediately prior to the date of termination, monthly reimbursement of the COBRA premiums for continued group health and dental plan coverage in which the Executive was enrolled as of immediately prior to the termination date, less active employee rates (which will be payable by the Executive), for a period of twelve (12) months following the termination date (or, if earlier, until the date the Executive becomes eligible to be covered under a subsequent employer's group health insurance plan (the amounts described in clauses (i) through (iii), collectively, the "**Severance Benefits**"); *provided that*, notwithstanding the foregoing, in the event that each of the Executive and RSI desires that the Executive continue in a position with RSI to be mutually agreed between Executive and RSI following Executive's termination of employment from the Company pursuant to this Section 5.4(a), the Executive shall not have any rights or entitlements to the Severance Benefits or any other severance or other payments under this Agreement, except for the Accrued Obligations, and the Executive's eligibility for any severance in connection with the Executive's subsequent termination of employment with RSI shall be governed by the terms and conditions of the RSI Employment Agreement. For the sake of clarity, the Severance Benefits will only be paid under this Agreement to the extent that the Executive's employment with the Company terminates in the circumstances described in this Section 5.4(a) and the Executive does not continue employment with RSI thereafter. The Executive agrees to provide the Company with written notice of the Executive's eligibility to be covered under a subsequent employer's group health insurance plan no later than five (5) business days after the Executive becomes eligible for such coverage.

(b) Notwithstanding anything to the contrary herein, the Severance Benefits shall be provided to Executive only if (A) Executive has timely executed and delivered to the Company a waiver and general release of claims, in a form to be provided promptly by the Company following the termination date (the "**Release**"), (B) Executive has not revoked or breached the provisions of such Release and (C) Executive has not violated the terms of the NDIA. If the period during which Executive may execute or revoke the Release spans two taxable years of Executive, the Severance Benefits shall in all events be paid to Executive in the second such taxable year, and any Severance Benefits that otherwise would have been payable during the first taxable year shall be paid in a lump sum in the first calendar month of the second taxable year. Executive acknowledges and agrees that the Company has no obligation to pay Executive any severance, except as expressly provided herein or as may otherwise be approved by the Company, and only to the extent Executive complies with the express contractual conditions hereof.

5.5. **Definitions**. For purposes of this Agreement, the following terms shall have the following meanings:

(a) "**Cause**" shall mean Executive's: (i) conviction of, or plea of guilty or no contest to, any (x) felony or (y) any other crime involving moral turpitude or dishonesty; (ii) participation in fraud, embezzlement, misappropriation or theft against any member of the Company or its direct or indirect subsidiaries and affiliates (collectively, the "**Company Group**"); (iii) material breach of this Agreement or any other agreement between Executive and any member of the Company Group that has not been cured (if curable) within thirty (30) days after receiving written notice of such breach; (iv) engagement in any conduct or act of gross negligence that causes, or is reasonably likely to cause, material damage to any member of the Company Group monetarily or otherwise (including, with respect to the reputation, business or business relationships of any member of the Company Group); (v) material failure to comply with the code of conduct or other material policies of any member of the Company Group; (vi) violation of any law, rule or regulation relating in any way to the business or activities of the Company Group, or any other law, rule or regulation that results in Executive's arrest, censure or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities; or (vii) willful failure to substantially perform Executive's duties hereunder (other than as a result of Disability (as defined below)) that has not been cured (if curable) within thirty (30) days after receiving written notice from the Company.

(b) "**Disability**" shall have the meaning assigned to such term in the RSI Employment Agreement.

(c) "**Good Reason**" shall mean the occurrence of any of the following events without Executive's consent: (i) a material reduction in Executive's Base Salary (*provided*, *however*, that if such reduction occurs in connection with a Company-wide decrease in the compensation of similarly situated employees of the Company, such reduction shall not constitute Good Reason if it is a reduction of a proportionally like percentage affecting all such similarly situated employees not to exceed ten percent (10%)); (ii) a material reduction of Executive's authority, duties or responsibilities, as compared to Executive's authority, duties or responsibilities immediately prior to such reduction; or (iii) a relocation of Executive to a primary office location more than twenty five (25) miles from Executive's primary company office location as of the Start Date (*provided* that Executive being permitted to work remotely shall not constitute Good Reason); *provided* that, in each case Executive (A) gives the Company written notice of Executive's intent to terminate employment for Good Reason within thirty (30) days following the first occurrence of the conditions that Executive believes constitute Good Reason, (B) the Company fails to remedy such conditions within thirty (30) days following receipt of the written notice from Executive and (C) Executive voluntarily terminates employment within thirty (30) days following the expiration of such cure period.

5.6. **Effect of Termination**. The Executive agrees that should the Executive's employment with the Company terminate for any reason, the Executive shall be deemed to have resigned from any and all positions as an officer of the Company and the Parent and any of its subsidiaries. The Executive may continue serving as a director of the Parent following such termination with the mutual written agreement of Parent and RSL.

5.7. **Section 409A Compliance**.

(a) It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), the Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "resignation," "termination," "termination of employment" or like terms shall mean separation from service. In no event may Executive, directly or indirectly, designate the calendar year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executive's execution of any release of claims, directly or indirectly, result in the Executive designating the calendar year of payment of any amounts of deferred compensation subject to Section 409A, and if a payment that is subject to execution of a release of claims could be made in more than one taxable year, payment shall be made in the later taxable year. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any compensation under this Agreement constitutes deferred compensation subject to Code Section 409A but does not satisfy an exemption from, or the conditions of, Code Section 409A.

(b) Notwithstanding any provision to the contrary in this Agreement, if the Executive is deemed by the Company at the time of a separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i), and if any payments or benefits that the Executive becomes entitled to under this Agreement on account of such separation from service are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments or benefits is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of separation from service, (ii) the date of the Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first (1st) business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred.

(c) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments shall be made on or before the last day of the Executive's taxable year following the taxable year in which the expense was incurred.

5.8. **Arbitration; Waiver of Jury Trial**. If any legally actionable dispute arises under this Agreement, the RSI Employment Agreement or otherwise which cannot be resolved by mutual discussion between the Parties, then the Company and Executive each agrees to resolve that dispute by binding arbitration pursuant to the terms and conditions of the Mutual Agreement to Arbitrate Claims (the "**Arbitration Agreement**") previously entered into between RSI and Executive, a copy of which is attached as Exhibit A hereto, it being understood that any reference to the "Company" in the Arbitration Agreement shall be interpreted to cover IMVT Corporation and its applicable subsidiaries and affiliates. The terms of the Arbitration Agreement are incorporated herein by reference and deemed to be a part of this Agreement. This Section 5.8 (and the Arbitration Agreement) shall survive the termination of Executive's employment. EACH PARTY EXPRESSLY WAIVES THE RIGHT TO TRIAL BY JURY IN ANY LAWSUIT OR PROCEEDING RELATING TO OR ARISING IN ANY WAY FROM THIS AGREEMENT OR THE MATTERS CONTEMPLATED HEREBY.

5.9. **Section 280G**. If Executive would be entitled to payments or benefits under this Agreement or under any other plan, program, agreement or arrangement that would constitute "parachute payments" as defined in Section 280G of the Code and could result in any such payment or benefit being subject to an excise tax under Section 4999 of the Code, the present value of Executive's payments and benefits will be reduced by the minimum amount necessary such that the aggregate present value of such payments and benefits do not trigger the excise tax; provided, however, no such reductions shall be given effect if Executive would be entitled to greater payments and benefits on an after-tax basis (taking into account the excise tax imposed pursuant to Section 4999 of the Code, any tax imposed by any comparable provision of state law, and any applicable federal, state and local income and employment taxes) than if such reductions were to be implemented. If payments or benefits are to be reduced, any such reduction in payments and/or benefits shall be made in accordance with Section 409A and shall occur in the manner that results in the greatest economic benefit to the Executive as determined by the Company's independent accountants. All determinations in applying the foregoing provisions for purposes of the "golden parachute" rules under Sections 280G and 4999 of the Code will be made by the Company's independent accountants and shall be final and binding on the parties.

6. **GENERAL PROVISIONS**.

6.1. **Representations and Warranties**.

(a) The Executive represents and warrants that the Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that the Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. The Executive represents and warrants that the Executive is not subject to any confidentiality or non-competition agreement or any other similar type of restriction that could restrict in any way the Executive's hiring by the Company and the performance of the Executive's expected job duties with the Company.

(b) The Company and its affiliates do not wish to incorporate any unlicensed or unauthorized material, or otherwise use such material in any way in connection with, its and their respective products and services. Therefore, the Executive hereby represents, warrants and covenants that the Executive has not and will not disclose to the Company or its affiliates, use in their business, or cause them to use, any information or material which is a trade secret, or confidential or proprietary information, of a third party, including, but not limited to, any former employer, competitor or client, unless the Company or its affiliates have a right to receive and use such information or material.

(c) The Executive represents and warrants that the Executive is not debarred and has not received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities. The Executive understands and agrees that this Agreement is contingent on the Executive's submission of satisfactory proof of identity and legal authorization to work in the United States, as well as verification of auditor independence.

6.2. **Advertising Waiver**. The Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning business of the Company in which the Executive's name and/or pictures of the Executive appear. The Executive hereby waives and releases any claim or right the Executive may otherwise have arising out of such use, publication or distribution.

6.3. **Miscellaneous**.

(a) This Agreement, along with the NDIA, the Mutual Agreement to Arbitrate Claims and any applicable equity awards that have been granted or will be granted pursuant to this Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations.

(b) This Agreement may not be modified or amended except in a writing signed by both the Executive and a duly authorized officer of the Company or a member of the Board.

(c) This Agreement will bind the heirs, personal representatives, successors and assigns of both the Executive and the Company, and inure to the benefit of both the Executive and the Company, and to the Executive's and the Company's heirs, successors and assigns, as applicable, except that the duties and responsibilities of the Executive are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its obligations hereunder, in connection with any merger, consolidation, or transfer or other disposition of all or substantially all of its assets, and such rights and obligations shall inure to, and be binding upon, any successor to the Company or any successor to all or substantially all of the assets of the Company, which successor shall expressly assume such obligations.

(d) If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable.

(e) This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New York as applied to contracts made and to be performed entirely within New York.

(f) Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

[*SIGNATURE PAGE FOLLOWS*]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

IMVT Corporation
/s/ Tiago Girao
Name: Tiago Girao
Title: Chief Financial Officer

ACCEPTED AND AGREED:
/s/ Eric Venker
Name: Eric Venker

Exhibit A

Mutual Agreement to Arbitrate Claims

[*Attached*]

Mutual Arbitration Agreement

IMVT Corporation ("Immunovant" or the "Company") and I, the undersigned employee, recognize and desire the benefits of a speedy, impartial, private and binding dispute resolution procedure. For these reasons, and in consideration of the mutual promises in this agreement to arbitrate ("Agreement") and benefits of our employment relationship, the Company and I mutually consent to the resolution by arbitration of all claims or controversies ("claims"), past, present or future, whether or not arising out of my employment (or its termination), as stated below.

Arbitrable claims. Arbitrable claims are those that the Company (or its subsidiaries and affiliates) may have against me or that I (and no other party) may have against any of the following: (1) the Company, (2) its officers, directors, employees or agents in their capacity as such or otherwise, (3) its parent, subsidiary and affiliated entities, (4) benefit plans or the plans' sponsors, fiduciaries, administrators, affiliates and agents, and/or (5) all successors and assigns of any of them. The only claims that are arbitrable are those that could be brought under applicable state or federal law and which lawfully can be the subject of an agreement to arbitrate. Arbitrable claims include, but are not limited to: claims for wages, bonuses, or other compensation due; claims for breach of any contract or covenant (express or implied); tort claims; claims for discrimination (including, but not limited to, race, sex, sexual orientation, religion, national origin, age, marital status, military or veterans status, physical or mental disability or handicap, or medical condition), harassment or retaliation; claims for benefits (except claims under an employee benefit or pension plan that either specifies that its claims procedure shall culminate in an arbitration procedure different from this one, or is underwritten by a commercial insurer which decides claims); and claims for violation of any federal, state, or other governmental law, statute, regulation, or ordinance, except claims for workers' compensation, unemployment compensation benefits, or state or federal disability insurance, claims for benefits under a plan that is governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), and claims that are subject to the exclusive jurisdiction of the National Labor Relations Board; or other dispute or claim that has been expressly excluded from arbitration by a governing federal statute. Both the Company and I agree that neither of us shall initiate or prosecute any lawsuit in any way related to any claim covered by this Agreement, other than to seek temporary equitable relief in aid of arbitration where such relief is available by law. I understand that nothing in this Agreement prohibits me from filing a complaint, charge, or other communication with any administrative or other governmental agency. However, any dispute or claim that is covered by this Agreement but not resolved through the federal, state, or local agency proceedings must be submitted to arbitration in accordance with this Agreement.

Law governing this Agreement. The Federal Arbitration Act shall govern the interpretation, enforcement and all proceedings pursuant to this Agreement. To the extent that the Federal Arbitration Act is inapplicable, or held not to require arbitration of a particular claim or claims, the arbitration law of the state in which I work or last worked for the Company shall apply.

Arbitration provider and rules. The arbitration will be conducted through Judicial Arbitration & Mediation Services (JAMS). The arbitration shall take place in the county (or comparable government unit) in which I am or was last employed by the Company, and no dispute affecting my rights or responsibilities shall be adjudicated in any other venue or forum.

The arbitration will be conducted in accordance with the then-current JAMS Employment Arbitration Rules & Procedures (and no other JAMS rules), which currently are available at http://www.jamsadr.com/rules-employment-arbitration. I understand that the Company will provide me a written copy of those rules upon my request. The arbitrator shall be either a retired judge, or an attorney who is experienced in employment law and licensed to practice law in the state in which the arbitration is convened (the "Arbitrator"), selected as provided by the JAMS rules. If a JAMS arbitrator is not available to conduct an arbitration in the location where the arbitration is to occur, then another arbitration service provider will be selected by mutual agreement of the parties (and all references to JAMS will be deemed to be references to that arbitration service provider). If the parties cannot agree on an alternative arbitration service provider, the court upon petition or motion shall designate one.

The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) of the state where I work or worked at the time the arbitrable dispute or claim arose, or federal law, or both, as applicable to the claim(s) asserted. The Arbitrator is without jurisdiction to apply any different substantive law or law of remedies. The Arbitrator has the authority to hear and rule on dispositive motions (such as motions for summary adjudication or summary judgment). The Federal Rules of Evidence shall apply. The Arbitrator shall render an award and written opinion, which shall include the factual and legal basis for the award, normally within 30 days after a dispositive motion is heard, or an arbitration hearing (including any post-hearing briefing) is completed.

Arbitration costs and fees. The Company will be responsible for paying any filing fee and the fees and costs of the Arbitrator; provided, however, that if I am the party initiating the claim, in the first instance, I will contribute an amount equal to the filing fee to initiate a claim in the court of general jurisdiction in the state in which I am (or was last) employed by the Company, unless the JAMS rules or the Arbitrator allow me to proceed without doing so based on demonstrated financial hardship. Each party shall pay its own litigation costs and attorneys' fees, if any. However, if any party prevails on a statutory claim which affords the prevailing party attorneys' fees and litigation costs, or if there is a written agreement providing for attorneys' fees and/or litigation costs, the Arbitrator shall rule upon a motion for attorneys' fees and/or litigation costs under the same standards a court would apply under the law applicable to the claim(s) at issue.

Procedure for asserting claims. The party asserting the claim must give written notice of any claim to the other party no later than the expiration of the statute of limitations (deadline for filing) that the law prescribes for the claim. Otherwise, the claim shall be deemed waived. I understand that the party asserting the claim is encouraged to give written notice of any claim as soon as possible after the event or events in dispute so that arbitration of any differences may take place promptly. Written notice to the Company, or its officers, directors, employees or agents, shall be sent to the Company's then-current headquarters address, c/o Head of Human Resources. I will be given written notice at the last address recorded in my personnel file. The written notice shall identify and describe the nature of all claims asserted, the facts upon which such claims are based and the relief or remedy sought. The notice shall be sent to the other party by certified or registered mail, return receipt requested.

Discovery. The Arbitrator may grant discovery if the Arbitrator finds that the party has demonstrated that it needs that discovery to adequately arbitrate the claim, taking into account the parties' mutual desire to have a speedy, less-formal, and cost-effective dispute-resolution mechanism.

Individual dispute resolution. To the maximum extent permitted by law, I hereby waive any right to bring on behalf of persons other than myself, or to otherwise participate with other persons in, any class, collective, or representative action, or other federal, state or local statute or ordinance of similar effect. I understand, however, that to the maximum extent permitted by law I retain the right to bring claims in arbitration, for myself as an individual (and only for myself). If a court adjudicating a case involving the Company and me were to determine that there is an unwaivable right to bring a class representative action, any such representative action shall be brought only in court, and not in arbitration. No arbitration award or decision will have any preclusive effect as to issues or claims in any dispute with anyone who is not a named party to the arbitration.

Finality. The decision of the Arbitrator will be final, conclusive and binding on the parties to the arbitration, except as provided by law. Judgment may be entered on the Arbitrator's decision in any court having jurisdiction.

Complete agreement. This is the complete agreement between the Company and me on the subject hereof; provided, however, that if for any reason this Agreement is held unenforceable, then any prior agreement to arbitrate between the Company and me shall survive. No party is relying on any representations, oral or written, on the subject of the effect, enforceability or meaning of this Agreement, except as specifically set forth in this Agreement. This Agreement shall survive the termination of my employment and the expiration of any benefit plan. Notwithstanding anything to the contrary, I acknowledge that this agreement shall supersede any prior agreement to arbitrate between the Company and me.

Company bound. I understand that, by the act of presenting this Agreement to me, the Company has agreed to bind itself to (and is entitled to invoke) this Agreement upon my execution of it, without need for a signature on its part.

Severability. If any provision of this Agreement is adjudged to be void or otherwise unenforceable, in whole or in part, such adjudication shall not affect the validity of the remainder of the Agreement. All other provisions shall remain in full force and effect based upon the mutual intent of the Company and me to create a binding agreement to arbitrate any disputes between us.

Not a contract of employment. This Agreement is not, and shall not be construed to create, any contract of employment, express or implied. Nor does this Agreement in any way alter the "at- will" status of Employee's employment.

I UNDERSTAND THAT I AM GIVING UP MY RIGHT TO A JURY TRIAL.

I FURTHER ACKNOWLEDGE THAT I HAVE BEEN GIVEN THE OPPORTUNITY TO DISCUSS THIS AGREEMENT WITH MY PRIVATE LEGAL COUNSEL, IF ANY, AND HAVE AVAILED MYSELF OF THAT OPPORTUNITY TO THE EXTENT I WISHED TO DO SO.

IMVT Corporation

/s/ Tiago Girao
Tiago Girao
Title: Chief Financial Officer
July 28, 2025

/s/ Eric Venker
Employee: Eric Venker
July 28, 2025

IMMUNOVANT, INC.

2019 EQUITY INCENTIVE PLAN
CAPPED VALUE APPRECIATION RIGHT AWARD GRANT NOTICE

Participant:	[NAME] (the "***Participant***")
Company:	Immunovant, Inc., a Delaware corporation (the "***Company***")
Plan:	Immunovant, Inc. 2019 Equity Incentive Plan (as amended, the "***Plan***")
Notice:	The Participant has been granted an award of Capped Value Appreciation Rights ("***CVARs***") in accordance with the terms of this Grant Notice (this "***Grant Notice***"), the Capped Value Appreciation Right Award Agreement attached hereto as Attachment A (the "***CVAR Award Agreement***" and, together with this Grant Notice, collectively, this "***Agreement***") and the Plan. Unless otherwise defined, capitalized terms used herein shall have the meanings ascribed to them in the Plan.
Type of Award:	A CVAR is an unfunded and unsecured conditional obligation of the Company that represents the right to receive the CVAR Amount (defined below), if any, applicable to the Participant's award of CVARs, subject to the terms and conditions of this Agreement and those of the Plan. A CVAR is an Other Stock Award for purposes of the Plan.
CVARs:	[#] CVARs
Grant Date:	[DATE] (the "***Grant Date***")
Vesting Commencement Date:	[DATE] (the "***Vesting Commencement Date***")
Expiration Date:	[DATE] (the "***Expiration Date***")
Hurdle Price:	$[●] per share of Common Stock (the "***Hurdle Price***")
Cap Price:	$[●] per share of Common Stock (the "***Cap Price***")
Knock-in Price:	$[●] per share of Common Stock (the "***Knock-in Price***")
Vesting:	The CVARs will vest on the first date that each of (i) the "***Service Requirement***", (ii) the "***Performance Requirement***" and (iii) the "***Knock-in Requirement***" have been satisfied (collectively, the "***Vesting Requirements***"). The portion of the CVARs that have satisfied all of the Vesting Requirements in accordance with this Agreement as of any relevant date of determination are referred to as the "***Vested CVARs***" and the date that all of the Vesting Requirements are satisfied with respect to any CVARs is referred to as the "***Vesting Date***" with respect to such CVARs. For purposes of this Agreement, "***Continuous Service***" shall be as defined in the Plan, and, for the sake of clarity, shall include the Participant's continued employment or service with Roivant Sciences Ltd. or one of its subsidiaries.
Service Requirement:	The Service Requirement applicable to the CVARs will be satisfied as follows, subject to the Participant's Continuous Service through each of the dates set forth below (each a "***Service Vesting Date***"): [●] The CVARs that are scheduled to satisfy the Service Requirement on an applicable Service Vesting Date are collectively referred to herein as a "***CVAR Tranche***".

Performance Requirement:	[●]
Knock-in Requirement:	The Knock-in Requirement applicable to any CVAR Tranche will be satisfied if, as of the relevant Service Vesting Date of such CVAR Tranche, the Fair Market Value of a share of Common Stock equals or exceeds the Knock-in Price. For the sake of clarity, the Knock-in Requirement will apply on a CVAR Tranche-by-CVAR Tranche basis (and satisfaction of the Knock-in Requirement by one applicable CVAR Tranche (i.e., by virtue of the Fair Market Value of a share of Common Stock being equal to or exceeding the Knock-in Price as of the Service Vesting Date applicable to such CVAR Tranche or a subsequent Knock-in Measurement Date) shall not constitute satisfaction of the Knock-in Requirement for any other CVAR Tranche). If the Fair Market Value of a share of Common Stock does not equal or exceed the Knock-in Price as of the relevant Service Vesting Date of a CVAR Tranche, then the CVAR Tranche that has otherwise satisfied the Service Requirement as of such Service Vesting Date will be deemed to remain outstanding and will be "re-tested" and eligible to become Vested CVARs on a subsequent annual "Knock-in Measurement Date" (as defined below), subject to (i) the Participant's Continuous Service through the applicable Knock-in Measurement Date on which the Knock-in Requirement is satisfied with respect to such CVAR Tranche and (ii) satisfaction of the Performance Requirement. For purposes of this Agreement, a "***Knock-in Measurement Date***" means [DATE]. For the sake of clarity, once the Knock-in Requirement with respect to any CVAR Tranche has been satisfied as of the Service Vesting Date applicable to a CVAR Tranche or a subsequent Knock-in Measurement Date, the Knock-in Requirement shall not be required to be subsequently satisfied. With respect to any CVAR Tranche that has not satisfied the Knock-in Requirement (i.e., by virtue of the Fair Market Value of a share of Common Stock equal or exceeding the Knock-in Price as of the Service Vesting Date applicable to such CVAR Tranche or a subsequent Knock-in Measurement Date) on or prior to the Expiration Date, such CVARs (the "***Unsatisfied CVARs***") will nonetheless be eligible to become Vested CVARs as of the Expiration Date, subject to (i) the Participant's Continuous Service through the Expiration Date and (ii) satisfaction of the Performance Requirement. Notwithstanding anything to the contrary herein, in the event of a Change in Control prior to the satisfaction of the Knock-in Requirement, the Knock-in Requirement shall be deemed to have been fully satisfied immediately upon the occurrence of such Change in Control (and, for the avoidance of doubt, the CVARs shall otherwise remain outstanding and eligible to vest based on achievement of the other applicable Vesting Requirements).
CVAR Amount and Payment Terms:	Subject to the satisfaction of the Vesting Requirements, as of each applicable Payment Date (as defined below), the Participant will be entitled to receive (subject to the satisfaction of Tax Withholding Obligations in accordance with the CVAR Award Agreement) an amount equal to the product of (i) the number of CVARs held by the Participant that became Vested CVARs on the applicable Vesting Date *multiplied by* (ii) the excess (if any) of (A) the Fair Market Value of a share of Common Stock on the applicable Vesting Date (up to the Cap Price) over (B) the Hurdle Price (the "***CVAR Amount***"), and the Vested CVARs will be cancelled in exchange for payment of the CVAR Amount. For the avoidance of doubt, (i) in no event will the Fair Market Value of a share of Common Stock used to determine the CVAR Amount be greater than the Cap Price and (ii) to the extent applicable, with respect to any Unsatisfied CVARs that become Vested CVARs as of [DATE], in the event the Fair Market Value of a Share of Common Stock as of [DATE] is less than the Hurdle Price, then such Unsatisfied CVARs shall not constitute Vested CVARs and will be immediately forfeited and cancelled without the payment of any consideration therefor. The CVAR Amount payable in respect of the applicable Vested CVARs will be settled and delivered within 30 days following the applicable Vesting Date of such Vested CVARs (such actual date of payment, the "***Payment Date***").

Form of Payment:	The CVAR Amount payable in respect of the Vested CVARs will be paid to the Participant in the form of shares of Common Stock (such shares of Common Stock, the "***CVAR Shares***"), with the number of such CVAR Shares to be determined by dividing (i) the applicable CVAR Amount by (ii) the Fair Market Value of a share of Common Stock on the applicable Payment Date (with any fractional CVAR Shares paid to the Participant in the form of cash).
Additional Terms/ Acknowledgements:	The Participant acknowledges receipt of, and understands and agrees to, this Agreement and the Plan. The Participant acknowledges and agrees that this Agreement may not be modified, amended or revised, except as provided in the Plan. By accepting this award of CVARs, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

IMMUNOVANT, INC.		**PARTICIPANT**	
Signature:		Signature:	
Print Name:		Print Name:	
Title:		Address:	

IMMUNOVANT INC.

2019 EQUITY INCENTIVE PLAN
CAPPED VALUE APPRECIATION RIGHT AWARD AGREEMENT

This Capped Value Appreciation Right Award Agreement ("***CVAR Award Agreement***"), dated as of the Grant Date set forth in the Capped Value Appreciation Right Grant Notice to which this CVAR Award Agreement is attached (the "***Grant Notice***"), is made between Immunovant Inc. and the Participant designated in the Grant Notice. The Grant Notice and the CVAR Award Agreement, collectively, are referred to herein as this "***Agreement***."

1. Definitions. Capitalized terms used but not defined herein have the meaning set forth in the Plan or the Grant Notice, as applicable.

2. Grant of Capped Value Appreciation Rights. Subject to the provisions of this Agreement and the provisions of the Plan, the Company hereby grants to the Participant the number of CVARs set forth in the Grant Notice.

3. Vesting and Forfeiture.

(a) The CVARs shall vest and become payable as set forth in the Grant Notice.

(b) Upon the termination of the Participant's Continuous Service for any reason (other than for Cause), (i) any CVARs that have become Vested CVARs prior to the date of such termination of Continuous Service (the "***Termination Date***") which have not yet been settled and cancelled, will be settled and cancelled on the applicable Payment Date in exchange for the applicable CVAR Amount in accordance with the Grant Notice, and (ii) any CVARs that have not become Vested CVARs will be automatically forfeited and cancelled without the payment of any consideration to the Participant, and the Participant shall have no further rights with respect to such CVARs.

(c) Notwithstanding anything to the contrary in this Agreement, in the event that (i) the Participant's Continuous Service is terminated for Cause or (ii) the Performance Requirement is not satisfied, then, in each case all of the Participant's CVARs shall be automatically forfeited without the payment of any consideration to the Participant, and the Participant shall have no further rights with respect to such CVARs.

4. Settlement of CVARs. The Company will settle and pay the Participant in respect of his or her Vested CVARs in accordance with the terms of the Grant Notice, in full settlement and satisfaction of the Vested CVARs, in each case, subject to satisfaction of applicable tax withholding obligations with respect thereto in accordance with Section 5 of this Agreement.

5. Taxes.

(a) You acknowledge that, regardless of any action taken by the Company or any Affiliate, the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, or any other tax of any kind related to the CVARs and legally applicable to you ("***Tax-Related Items***") is and remains your responsibility (or that of your beneficiary). You further acknowledge that the Company (i) makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the CVARs, including, but not limited to, the grant, vesting or settlement of the CVARs or the subsequent sale of shares of Common Stock acquired upon settlement of the CVARs and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of the CVARs to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result.

(b) Unless otherwise determined by the Committee, upon the vesting and/or settlement of the CVARs (or as of any other date on which the value of any CVARs otherwise become includible in your gross income for tax purposes) (the "***Tax Withholding Date***"), you shall be required to pay to the Company, and the Company shall have the right to deduct from any compensation paid to you pursuant to the CVARs, the amount of any applicable federal, state, local and foreign Tax-Related Items that the Company determines must be withheld with respect to the CVARs (the "***Tax Withholding Obligations***"). By execution of this Agreement, you hereby consent to, and authorize the Company to, on your behalf, instruct a registered broker chosen by the Company, at a time when you are not in possession of material nonpublic information, to sell on or as soon as administratively practicable following the applicable Tax Withholding Date, such number of shares of Common Stock (rounded up to the next whole number) as the Company deems necessary to satisfy (i) the Tax Withholding Obligations and (ii) all applicable fees and commissions due to, or required to be collected by, the broker (the "***Broker Fees***"), and the broker shall (A) be required to directly remit to the Company the portion of the cash proceeds from such sale necessary in order for the Company to satisfy the Tax Withholding Obligations and (B) retain the portion of the cash proceeds from such sale required to cover the Broker Fees relating directly to such sale (the "***Sell-to-Cover Method***"). Any excess Tax Withholding Obligations and Broker Fees not satisfied by the Sell-to-Cover Method as a result of insufficient proceeds from the sales pursuant thereto shall be automatically satisfied by the Company withholding such additional amounts through payroll necessary to satisfy any such remaining Tax Withholding Obligations and Broker Fees. To the extent the proceeds of such sales pursuant to the Sell-to-Cover Method exceed the Tax Withholding Obligations and the associated Broker Fees, the Company agrees to remit, or to cause the Broker to remit, to you such excess cash (without interest) as soon as administratively practicable thereafter. You hereby agree and acknowledge that the Company and the broker are under no obligation to arrange for the sale of shares of Common Stock at any particular price under the Sell-to-Cover Method and that the broker may affect sales as provided hereunder in one or more sales and that the average price for executions resulting from bunched orders may be assigned to your account. Your further agree and acknowledge that you will be responsible for all brokerage fees and other costs of sale associated with the Sell-to-Cover Method, and you agree to indemnify and hold the Company and the broker harmless from any losses, costs, damages, or expenses relating to any such sale. In connection with the Sell-to-Cover Method, you shall execute any such documents requested by the broker or the Company in order to effectuate the Sell-to-Cover Method and payment of the Tax Withholding Obligations, and you agree and acknowledge that the Sell-to-Cover Method shall be subject to additional terms, conditions and documentation determined to be necessary or appropriate by the Company or the applicable broker in furtherance of this Section 11(b). You acknowledge that this Section 11(b) (and the Sell-to-Cover Method contemplated hereby) is intended to comply with Section 10b5-1(c)(1) under the Exchange Act and shall be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act.

(c) Notwithstanding anything to the contrary herein, the Company may, in its discretion, permit or require you to satisfy the Tax Withholding Obligations, in whole or in part, through a method other than the Sell-to-Cover Method described in Section 5(b), including by (i) causing you to tender a cash payment sufficient to satisfy the Tax Withholding Obligations, (ii) withholding from payroll or from any amounts otherwise payable to you by the Company or any Affiliate in an amount sufficient to satisfy the Tax Withholding Obligations or (iii) by such other method as may be permitted under the Plan or as may be acceptable to the Board.

6. No Rights as a Shareholder Prior to Issuance of Common Stock. Neither the Participant nor any other person shall become the beneficial owner of the shares of Common Stock underlying the CVARs, nor have any rights to voting, dividends or other rights as a shareholder with respect to any such shares of Common Stock, until and after such shares of Common Stock, if any, have been actually issued to the Participant and transferred on the books and records of the Company or its agent in accordance with the terms of the Plan and this Agreement.

7. Transferability. The CVARs shall not be transferable other than by will or the laws of descent and distribution; *provided*, *however*, that the Committee may, in its discretion, permit the CVARs to be transferred subject to such conditions and limitations as may be imposed by the Committee.

8. Capitalization Adjustments. The number of CVARs, class of securities subject to the CVARs and the Cap Price applicable to the CVARs, each as set forth in the Grant Notice, will be adjusted for Capitalization Adjustments.

9. No Right as Employee or Consultant. Neither the grant of the CVARs nor any terms contained in this Agreement shall (a) affect in any manner whatsoever the right or power of the Company or any Subsidiary of the Company, to terminate the Participant's service for any reason, with or without cause, (b) if applicable, affect the Participant's status as an at-will employee of the Company who is subject to termination of service without cause, (c) confer upon the Participant any right to remain employed by or in service to the Company or any Subsidiary of the Company, (d) interfere in any way with the right of the Company or any Subsidiary of the Company at any time to terminate such employment or service, or (e) affect the right of the Company or any Subsidiary of the Company to increase or decrease the Participant's other compensation.

10. The Plan. By accepting any benefit under this Agreement, the Participant and any person claiming a benefit under or through the Participant shall be conclusively deemed to have indicated his or her acceptance and ratification of, and consent to, all of the terms and conditions of the Plan and this Agreement and any action taken under the Plan by the Board, the Committee or the Company, in any case in accordance with the terms and conditions of the Plan. This Agreement is subject to all the terms, provisions and conditions of the Plan, which are incorporated herein by reference, and to such rules, policies and regulations as may from time to time be adopted by the Committee. In the event of any conflict between the provisions of the Plan and this Agreement, the provisions of the Plan shall control, and this Agreement shall be deemed to be modified accordingly.

11. Compliance with Laws and Regulations.

(a) The CVARs and the obligation of the Company to deliver any shares of Common Stock or cash hereunder shall be subject in all respects to (i) all applicable federal and state laws, rules and regulations and (ii) any registration, qualification, approvals or other requirements imposed by any government or regulatory agency or body which the Committee shall, in its discretion, determine to be necessary or applicable. Moreover, the Company shall not deliver any certificates for shares of Common Stock to the Participant or any other person pursuant to this Agreement if doing so would be contrary to applicable law. If at any time the Company determines, in its discretion, that the listing, registration or qualification of shares of Common Stock upon any national securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body, is necessary or desirable, the Company shall not be required to deliver any certificates for shares of Common Stock to the Participant or any other person pursuant to this Agreement unless and until such listing, registration, qualification, consent or approval has been effected or obtained, or otherwise provided for, free of any conditions not acceptable to the Company.

(b) If at any time the shares of Common Stock are not registered under the Securities Act, and/or there is no current prospectus in effect under the Securities Act with respect to the shares of Common Stock, the Participant shall execute, prior to the delivery of any shares of Common Stock to the Participant by the Company pursuant to this Agreement, an agreement (in such form as the Company may specify) in which the Participant represents and warrants that the Participant is acquiring the shares of Common Stock acquired under this Agreement for the Participant's own account, for investment only and not with a view to the resale or distribution thereof, and represents and agrees that any subsequent offer for sale or distribution of any kind of such shares of Common Stock shall be made only pursuant to either (i) a registration statement on an appropriate form under the Securities Act, which registration statement has become effective and is current with regard to the shares of Common Stock being offered or sold; or (ii) a specific exemption from the registration requirements of the Securities Act, but in claiming such exemption, the Participant shall, prior to any offer for sale of such shares of Common Stock, obtain a prior favorable written opinion, in form and substance satisfactory to the Company, from counsel for or approved by the Company, as to the applicability of such exemption thereto.

(c) The Participant's CVARs and any obligation of the Company to deliver the underlying shares of Common Stock, if any, upon settlement of the CVARs shall be subject in all respects to (i) all applicable federal and state laws, rules and regulations, (ii) any regulation, qualification, approvals or other requirements imposed by any government or regulatory agency or body which the Board shall, in its sole discretion, determine to be necessary or applicable and (iii) the terms of any Shareholders Agreement entered into by and among the Company and each of the shareholders of the Company that is a party thereto, as may be amended or in effect from time to time (the "***Shareholders Agreement***"). Moreover, the CVARs may not be settled if its settlement, or the receipt of shares of Common Stock pursuant thereto, would be contrary to applicable law. Any shares of Common Stock received upon any settlement of the CVARs shall be held subject to all of the terms and conditions of the Shareholders Agreement. The Participant hereby agrees to execute and become a party to the Shareholders Agreement as a condition to the grant of the CVARs and be subject to the rights and obligations thereunder, and the Company may require the Participant to execute a joinder to the Shareholders Agreement in connection with the settlement of the CVARs for shares of Common Stock.

12. Market Standoff Agreement. The Participant agrees that in connection with any registration of the Company's securities that, upon the request of the Company or the underwriters managing any public offering of the Company's securities, the Participant will not sell or otherwise dispose of any shares of Common Stock without the prior written consent of the Company or such underwriters, as the case may be, for such reasonable period of time after the effective date of such registration as may be requested by such managing underwriters and subject to all restrictions as the Company or the underwriters may specify. The Participant will enter into any agreement reasonably required by the underwriters to implement the foregoing.

13. Notices. Any notices provided for in this Agreement or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to the Participant, five (5) days after deposit in the United States mail, postage prepaid, addressed to the Participant at the last address the Participant provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this award by electronic means or to request the Participant's consent to participate in the Plan by electronic means. By accepting this award, the Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

14. Other Plans. The Participant acknowledges that any income derived from any CVARs shall not affect the Participant's participation in, or benefits under, any other benefit plan or other contract or arrangement maintained by the Company or any Subsidiary of the Company.

15. Sections 409A. The CVARs and all payments made pursuant to this Agreement are intended to be exempt and/or comply with Sections 409A of the Code, and shall be interpreted on a basis consistent with such intent. However, nothing herein will be construed as a guarantee by the Company of any particular tax effect to the Participant under this Agreement. The Company will not be liable to the Participant for any additional tax, penalty or interest that may be imposed on the Participant pursuant to Sections 409A of the Code or damages incurred by the Participant as a result of this Agreement (and the payment and benefits hereunder) failing to comply with, or be exempt from, Sections 409A of the Code.

Exhibit 10.7

Special Equity Award Opportunity Letter

Eric Venker
President and Chief Operating Officer

July 26, 2024

Dear Eric,

As a key employee of Roivant Sciences, Inc. ("**Roivant**"), we consider you integral to the future success of our business. Accordingly, we are pleased to provide you with the potential opportunity to receive one or more special grants of performance-based restricted stock units ("**PSUs**") in the future based on an assessment of your contributions to Roivant and its business, subject to, and in accordance with, the terms and conditions set forth in this letter (this "**Letter**").

During the period beginning on the date of this Letter and ending on the fifth (5^{th}) anniversary hereof (the "**Assessment Period**"), the Compensation Committee of the Board of Directors of Roivant Sciences Ltd. (the "**Committee**") will review and assesses, on a quarterly basis, whether you have made contributions to Roivant's business over time that include your successful delivery of value to Roivant and its business beyond and outside the normal operating context (the "**Contribution Condition**"). The Committee may, following the date of this Letter, identify additional specified criteria that it will take into account when making future determinations as to whether or not you have satisfied the Contribution Condition (which may include, solely by way of example, the Committee's determination that you have successfully identified an off-the-run investment opportunity that results in 10-figure value creation for Roivant or your taking on additional operating roles that directly lead to unanticipated blockbuster revenue outcomes due specifically to your ideas and execution). The determination as to whether or not you have satisfied the Contribution Condition during the Assessment Period will be made by the Committee in its sole and absolute discretion.

In the event that the Committee determines, in its sole discretion, that you have satisfied the Contribution Condition during the Assessment Period, the Committee will grant to you one or more special awards of PSUs, with the aggregate number of such PSUs that may be granted to you pursuant to all such awards not to exceed 11,900,000 PSUs (the actual number of PSUs, if any, granted to you in the future pursuant to this Letter, the "**Special PSUs**"). Your eligibility to receive any grant of Special PSUs and the aggregate number of Special PSUs granted to you, if any, will be determined by the Committee in its sole and absolute discretion in accordance with this Letter.

Any Special PSUs actually awarded to you by the Committee under this Letter will be granted pursuant to the terms of the Roivant Sciences Ltd. 2021 Equity Incentive Plan (as amended from time to time, and together with any successor plan thereto, the "**EIP**") and an award agreement thereunder, substantially in the form attached hereto as Exhibit A (the "**Special PSU Award Agreement**"). The effective date upon which the Committee approves any grant of any Special PSUs (or any portion thereof) to you in accordance with this Letter shall be the "Grant Date" for purposes of the Special PSU Award Agreement evidencing the applicable grant of Special PSUs (or portion thereof), which shall be determined on a grant-by-grant basis. To the extent that the Committee determines in its sole discretion that you have not satisfied the Contribution Condition during the Assessment Period, then you will not receive any grant of Special PSUs and the opportunity provided to you under this Letter will be forfeited and cancelled in its entirety without any payment to you.

The Special PSUs described in this Letter are in addition to the award by the Committee of restricted stock units and stock options under the EIP, to be granted on or about the date hereof.

The grant to you of any Special PSUs is subject to (i) your continued full-time employment with Roivant or one of its affiliates in good standing (including, without limitation, good performance and adherence to company policies) through the applicable grant date(s), which such good standing determination shall be made by the Committee in its sole discretion), (ii) the Committee's determination, in its sole discretion, of your satisfaction of the Contribution Condition during the Assessment Period and (iii) the terms and conditions set forth in this Letter, the EIP and the Special PSU Award Agreement.

We thank you in advance for your future efforts to the success of Roivant and our business.

Best Regards,

Roivant Sciences Ltd.

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

Exhibit A

Special PSU Award Agreement