2025

Annual Report

roivant

Dear Shareholders,

So much changed for us in the 12 months since our last shareholder letter that it feels almost impossible to write a reasonable update. 2025 was, by any measure, a transformative year for us. Our programs have gone from "high potential" to something much more tangible (and it shows in the way investors view us today). Brepocitinib has generated exciting in-human data in its first indication and has received Priority Review designation from FDA, we have generated several exciting datasets in other indications and programs, and we secured a settlement with Moderna for up to $2.25bn, of which $950m has already been paid. We are humbled by how dramatically the year's events changed our trajectory. Biotech demands humility; human biology, clinical trials and capital markets each have a way of defying expectations. We are grateful for the position we now occupy, and we are committed to maximizing this opportunity the same way we arrived here – through ruthless financial discipline and maniacal focus on clinical (and now commercial) execution.

Brepocitinib in dermatomyositis (DM). In September 2025, we reported topline results from the Phase 3 VALOR study: brepocitinib 30 mg met its primary endpoint (TIS change from baseline) and all nine key secondary endpoints. This is a disease that has never had an approved modern therapy, where patients have historically cycled through onerous IVIG infusions, high dose steroids and immunosuppressents, and off-label therapies many of which failed when studied in DM. The data were published in the *New England Journal of Medicine* in March 2026. The FDA accepted our NDA with Priority Review, with a PDUFA date in the current calendar quarter.

I want to be careful not to over-celebrate before the launch has actually happened. This drug is not yet in the hands of doctors and patients. But the VALOR data are robust, and we are excited for the opportunity to make it available if it is approved by FDA.

Brepocitinib beyond DM. One of the things I am most proud of this year is that we have not treated DM as the finish line. While advancing toward a potential first commercial launch for the drug, we continued to expand into new areas. In February 2026, brepocitinib delivered compelling Phase 2 results in cutaneous sarcoidosis—another disease with no approved therapies and where no placebo-controlled study had previously demonstrated benefit. The strength and consistency of our data led to FDA Breakthrough Therapy Designation, and we expect to begin a Phase 3 program in the second half of this calendar year. More broadly, these results reinforce our belief that brepocitinib has the potential to become an important medicine across many immune-mediated diseases, not just dermatomyositis.

We also enrolled the first patients in a Phase 2b/3 trial in lichen planopilaris in April 2026, and our Phase 3 program in non-infectious uveitis (NIU) enrolled rapidly with data expected in the second half of this year. Brepocitinib is not a one-indication molecule, and the pipeline behind DM is substantial; we expect it will continue to grow in time.

IMVT-1402. Immunovant made meaningful progress in its development of IMVT-1402 over 2025. In difficult-to-treat rheumatoid arthritis (D2T RA)—a population that has, by definition, failed multiple prior therapies—IMVT-1402 demonstrated compelling clinical activity in the open label portion of a Phase 2b trial, further reinforcing our confidence in the molecule and opening a new opportunity for further study. Those results show build on the additional Graves' disease data from batoclimab reported last September, which suggest the possibility that some patients may experience durable remission and that FcRNs could be a disease-modifying therapy for GD patients. Together, these findings strengthen our conviction that FcRn inhibition with a molecule optimized for deep IgG reduction can achieve outcomes in autoimmune disease even where other approaches have failed. We continue to actively develop IMVT-1402 in six indications (D2T RA, Graves' disease, myasthenia gravis, chronic inflammatory demyelinating polyneuropathy (CIDP), Sjögren's disease and cutaneous lupus erythematosus) – and are evaluating more to come.

Not every program advanced. In April 2026, both Phase 3 studies of batoclimab in thyroid eye disease failed to meet their primary endpoints, and we subsequently discontinued development of that molecule. While it was a disappointing outcome for a program in which we had invested significant time and resources, the results did not change our conviction in the underlying biology. If anything, subsequent analyses strengthened our belief that the key determinant of clinical benefit is achieving sufficiently deep and sustained IgG reduction—precisely what we believe IMVT-1402 can deliver.

Genevant. In March 2026, Genevant Sciences and Arbutus Biopharma reached a $2.25 billion global settlement with Moderna, ending all pending patent-infringement litigation with them. Moderna has paid $950 million in July 2026, with an additional $1.3 billion to be paid contingent on a resolution of Moderna's Section 1498 appeal in Genevant's favor. IP litigation at this scale is never a certainty, and our legal teams spent years building our case. These payments further strengthen our balance sheet and extend our financial runway in a period with a lot going on, and have facilitated additional capital return to shareholders as well.

Capital allocation. We ended the fiscal year with $4.3 billion in cash and marketable securities — before the Moderna payment. During the year, we completed our initial $1.5 billion share repurchase program, reducing our outstanding share count by over 15% from March 2024, when the repurchase program was first announced. Our board subsequently approved a total of $1 billion in share repurchases, with a $500 million repurchase program approved in June 2025 and an additional $500 million approved in March 2026 following the signing of the Moderna settlement. We intend to remain disciplined, both in maintaining sufficient funds for our high-value programs, and in returning excess capital to shareholders.

Though it is hard to believe, the next 12 months has even more coming than the last: the brepocitinib DM launch, NIU Phase 3 data, the mosliciguat PH-ILD Phase 2 readout, IMVT-1402 data in CLE and further updates from the D2T RA trial. IMVT-1402 readouts across multiple registrational programs, including in Graves' disease, are expected in 2027.

Finally, one thought is worth reflecting on: assuming FDA approval, brepocitinib will soon be widely available in the US. Of course that matters because we hope for commercial success, but equally important it means patients with dermatomyositis, living today with uncontrolled disease and an endless cycle of prednisone and methotrexate and IVIG, will finally have a new treatment option. After more than a decade of building Roivant, there is no greater validation of our work than moments like this – Brepo's approval in DM would be the ninth FDA approval for a drug developed in significant part by Roivant. It is why we exist: to improve the lives of patients by accelerating the development and commercialization of medicines that matter.

Matt Gline | Chief Executive Officer

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

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2026
OR

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

For the transition period from _____to_____
Commission File Number: 001-40782

ROIVANT SCIENCES LTD.

(Exact name of Registrant as specified in its Charter)

Bermuda (State or other jurisdiction of incorporation or organization)	98-1173944 (I.R.S. Employer Identification No.)
7th Floor 50 Broadway London SW1H 0DB United Kingdom	Not Applicable
1 Pennsylvania Plaza 54th Floor New York, NY United States[1]	10119
Viaduktstrasse 8 4051 Basel Switzerland[1] (Address of principal executive offices)	Not Applicable (Zip Code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

---

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of September 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common shares, par value $0.0000000341740141 per share (the "common shares"), held by non-affiliates of the registrant was approximately $9.8 billion, based on the closing price of the common shares on The Nasdaq Global Select Market on September 30, 2025 of $15.13 per share.

As of May 12, 2026 there were 719,270,385 common shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement to be issued in conjunction with the registrant's 2026 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended March 31, 2026, are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the registrant's proxy statement shall not be deemed to be a part of this Annual Report on Form 10-K.

[1] Addresses of wholly-owned subsidiaries of the Registrant.

TABLE OF CONTENTS

		Page
PART I.		
Item 1.	Business	7
Item 1A.	Risk Factors	56
Item 1B.	Unresolved Staff Comments	131
Item 1C.	Cybersecurity	131
Item 2.	Properties	132
Item 3.	Legal Proceedings	133
Item 4.	Mine Safety Disclosures	133
PART II.		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	134
Item 6.	[Reserved]	136
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	137
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	153
Item 8.	Financial Statements and Supplementary Data	154
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	203
Item 9A.	Controls and Procedures	203
Item 9B.	Other Information	205
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	205
Part III.		
Item 10.	Directors, Executive Officers and Corporate Governance	206
Item 11.	Executive Compensation	206
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	206
Item 13.	Certain Relationships and Related Transactions, and Director Independence	206
Item 14.	Principal Accountant Fees and Services	206
Part IV.		
Item 15.	Exhibits, Financial Statement Schedules	207
Item 16.	Form 10-K Summary	211
	Signatures	212

In this Annual Report on Form 10-K, unless otherwise stated or as the context requires, references to "Roivant," the "Company," "we," "us," "our" or similar references refer to Roivant Sciences Ltd., together with its consolidated subsidiaries.

Forward-Looking Statements

This Annual Report on Form 10-K contains statements, including matters discussed under Part I, Item 1A. "Risk Factors," Part I, Item 3. "Legal Proceedings" and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this report, that are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (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 Annual Report on Form 10-K 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 fact that we will likely incur significant losses for the foreseeable future and may never achieve sustained profitability;
- the fact that Immunovant relies on a license agreement with HanAll Biopharma Co., Ltd. to provide the rights to the core intellectual property relating to IMVT-1402 and batoclimab;
- the allocation of capital and personnel across our businesses;
- our Vant structure;
- potential future payments we may owe in connection with our product candidates;
- changes in tariffs and other governmental trade policies;
- unfavorable, uncertain and rapidly changing global and regional economic, political and public health conditions;
- acquisitions, divestitures and other strategic transactions;
- the use of our cash, cash equivalents and marketable securities;
- our significant holdings of cash, cash equivalents and marketable securities;
- the potential future need for additional capital to fund our operations;
- our business strategy and potential for future growth relying on a number of assumptions, some or all of which may not be realized;

- the inadequacy or uncertainty of funding levels for the Food and Drug Administration ("FDA"), United States Patent and Trademark Office ("USPTO"), Securities and Exchange Commission ("SEC") or other government agencies;

- a portion of our or certain of our Vants' manufacturing, laboratory research or clinical trial activities taking place in Asia and the possibility of a significant disruption in that region, such as a trade war or political unrest;

- legislation targeting biotechnology companies with ties to certain foreign adversaries, including the BIOSECURE Act;

- clinical trials and preclinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;

- the results of our preclinical studies and clinical trials not supporting 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 not being predictive of future trial results;

- interim, preliminary or topline data from our clinical trials changing as more patient data become available and are subject to audit or verification procedures;

- difficulties we may encounter enrolling and retaining patients in clinical trials, which could delay or otherwise adversely affect clinical development activities;

- 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 following regulatory approval or result in negative consequences;

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

- our products remaining subject to extensive regulatory scrutiny following regulatory approvals;

- our potential development of product candidates for the treatment of conditions for which there is little clinical experience and, in some cases, our use of new endpoints or methodologies;

- our failure to maintain or continuously improve our quality management program;

- the fact that 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;

- receipt of marketing approval for our product candidates not guaranteeing that they will achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success;

- our reliance on third parties to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable requirements;

- our not having our own manufacturing capabilities and reliance on third parties to produce clinical and commercial supplies of our product candidates;
- significant competition in an environment of rapid technological and scientific change, and the possibility that our competitors may achieve certain regulatory approvals before us or develop therapies that are safer, more advanced or more effective than ours;
- our dependence on our key personnel and our ability to attract, motivate and retain highly qualified personnel;
- the fact that use of artificial intelligence ("AI") could expose us to liability or adversely affect our business;
- our ability to obtain and maintain patent and other intellectual property protection for our technology and product candidates;
- the failure to issue of the patent applications that we own or in-license with respect to our product candidates if their validity, patentability, enforceability, breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our product candidates;
- the inadequacy of the length of our patent terms to protect the competitive position of our product candidates for an adequate amount of time;
- the fact that if our performance does not meet market expectations, the price of our securities may decline;
- the fact that 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;
- additional dilution of the percentage ownership of our shareholders 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 I, Item 1A. "Risk Factors."

These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. In addition, 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, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with our shareholders and the public about our company, our product candidates and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Summary Risk Factors

You should consider carefully the risks described under "Risk Factors" in Part I, Item 1A. of this Annual Report on Form 10-K. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

- 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.

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

- 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 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 we may owe in connection with our product candidates.

- Changes in tariffs and other governmental trade policies could negatively affect our business and results of operations.

- Unfavorable, uncertain and rapidly changing global and regional economic, political and public health conditions could adversely affect our business, financial condition and results of operations.

- 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 face risks in the future relating to the need for additional capital to fund our operations.

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

- Inadequate or uncertain funding levels for the FDA, USPTO, SEC or other government agencies, including from government shut downs or significant changes in leadership personnel or policies, could hinder, delay or result in the suspension of those agencies' operations, which could harm our business.

- 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.

- Legislation targeting biotechnology companies with ties to certain foreign adversaries, including the BIOSECURE Act, could materially adversely affect our business, supply chain and results of operations.

- 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.

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

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

- 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 of our product candidates, our business will be substantially harmed.

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

- Our product candidates may cause 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 make efforts to, or be able to, obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

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

- 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.

- 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.

- 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.

- 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.

- 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.

Industry and Market Data

We obtained the industry and market data included in this Annual Report on Form 10-K from our own research as well as from industry and general publications, surveys and studies conducted by third parties. Industry and general publications, studies and surveys generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. These third parties may, in the future, alter the manner in which they conduct surveys and studies regarding the markets in which we operate our business. As a result, you should carefully consider the inherent risks and uncertainties associated with the industry and market data contained in this Annual Report on Form 10-K, including those discussed in Part I, Item 1A. "Risk Factors."

[This page intentionally left blank]

PART I

ITEM 1. BUSINESS

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 JAK1 and TYK2 currently under review at the FDA for the treatment of dermatomyositis and also in late stage development for the treatment of non-infectious uveitis, cutaneous sarcoidosis and lichen planopilaris; IMVT-1402, a fully human monoclonal antibody 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.

Pipeline

The following table summarizes selected product candidates from our pipeline.

Product Candidate	Indication	Vant	Modality	Phase
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	PDUFA Date 3Q 2026
Brepocitinib	Non-Infectious Uveitis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Cutaneous Sarcoidosis	Priovant	Small Molecule	Phase 3*
Brepocitinib	Lichen Planopilaris	Priovant	Small Molecule	Phase 2b/3*
IMVT-1402	Difficult-to-Treat Rheumatoid Arthritis	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Graves' Disease	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Myasthenia Gravis	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Chronic Inflammatory Demyelinating Polyneuropathy	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Sjögren's Disease	Immunovant	Biologic	Phase 2/3*
IMVT-1402	Cutaneous Lupus Erythematosus	Immunovant	Biologic	Phase 2
Mosliciguat	Pulmonary Hypertension associated with Interstitial Lung Disease	Pulmovant	Inhaled	Phase 2

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

** Indicates registrational or potentially registrational trials.*

The Vant Model

The Vant model unlocks key strategic advantages for Roivant and, we believe, ultimately enables us to develop transformative medicines for diseases for which there are no approved therapies or where the current standard of care treatment has significant limitations faster than our competitors. We believe we are uniquely positioned to accomplish this by:

- ***Leveraging our business development expertise to identify and in-license promising drug candidates:*** We assembled our product candidate pipeline by leveraging our business development expertise and vast network

of industry relationships to relentlessly pursue opportunities to in-license or acquire programs where we believe we can deliver successful outcomes on accelerated timelines. Our pipeline expansion has been enabled by our strong track record of rapid and high-quality execution, as well as our ability to maintain a robust balance sheet to fund programs through development.

- ***Creating nimble, entrepreneurial Vants****:* Vants operate similarly to independent biotechnology companies where each management team is focused on its respective mission and is economically incentivized to maximize value through Vant-specific equity grants. Each of our Vant teams is built with deep relevant expertise to ensure successful execution of its particular development strategy. The Vant model is designed to facilitate rapid decision making and calculated risk taking, by empowering, aligning and incentivizing Vant teams around the outcomes of their specific product candidates.

- ***Allocating capital to maximize R&D efficiency:*** We apply an objective, rigorous decision-making framework across the drug development process designed to ensure resources and capital are continuously directed towards programs we believe have the highest probability of success and away from those that fail to meet our rigorous internal hurdles. We centralize capital allocation decisions at the Roivant level, while distributing operational decisions to the Vants, allowing us to strategically deploy capital in high growth areas, regardless of potentially competing operational priorities.

- ***Maintaining a diversified pipeline with various risk profiles:*** We have built a broad and differentiated pipeline that includes several drug candidates across different therapeutic areas, phases of development, modalities and geographies. This approach limits our exposure to concentrated scientific and biological risks and allows us to pursue multiple innovative hypotheses across our portfolio as we seek to develop therapies for patient populations with high unmet need.

- ***Designing creative "win-win" deal structures:*** We structure our partnerships to balance risk and the potential for future value creation. We ensure a significant proportion of near-term expenses go toward development, allowing us to stage our investment and align incentives as well as limit losses in the event of a setback. Our scale and proven track record of developing successful product candidates assures partners we are uniquely capable of maximizing value for patients and investors.

- ***Developing and deploying proprietary technologies:*** We believe we are able to develop transformative medicines faster by building and applying computational tools to drug discovery, development and commercialization. We occupy a unique position at the intersection of biopharma and technology, having built our capabilities in parallel, optimizing each for synergy with the other, in contrast to big pharma who have added software tools to legacy workflows or technology startups that lack experience developing drugs. Vants have access to, and are supported by, these technologies.

- ***Providing operating leverage through centralized support functions:*** Our model allows us to accelerate Vant formation and maturation by centralizing and sharing certain support functions across various Vants. Vants also benefit from access to our vast network of scientific experts, physicians and technologists to help optimize their clinical development activities and commercialization efforts.

The structural advantages of the Vant model combined with our "force of will" culture and investor mindset have enabled us to achieve an impressive track record: Since Roivant's founding in 2014, we have received 8 FDA approvals and completed 14 large registrational Phase 3 studies – 12 of which have yielded positive data (inclusive of approvals and Phase 3 studies from Vants transferred to Sumitomo Pharma and at Dermavant, which was acquired by Organon in October 2024).

Key Business Highlights

- **Roivant**

  - Reported consolidated cash, cash equivalents and marketable securities of $4.3 billion as of March 31, 2026, supporting cash runway into profitability.

- **Brepocitinib**

- Announced positive data in the Phase 3 VALOR study of brepocitinib in dermatomyositis ("DM"); brepocitinib 30 mg demonstrated clinically meaningful and statistically significant improvement compared to placebo on the primary endpoint and all nine key secondary endpoints, and the safety profile was consistent with previous clinical trials of brepocitinib. The FDA accepted brepocitinib's New Drug Application ("NDA") in DM with Priority Review and assigned a target action date in the third quarter of calendar year 2026. Commercial launch of brepocitinib in DM expected by the end of September 2026.

- Completed enrollment in the ongoing Phase 3 CLARITY study of brepocitinib in non-infectious uveitis ("NIU"); topline data expected in the second half of calendar year 2026.

- Announced positive results in the Phase 2 BEACON study of once-daily oral brepocitinib in cutaneous sarcoidosis ("CS"). Brepocitinib 45 mg demonstrated statistically significant improvements in CS disease activity, achieving a 22.3-point improvement in mean CSAMI-A at Week 16 versus a 0.7-point improvement in placebo. Brepocitinib demonstrated rapid, deep and sustained improvements across all other efficacy endpoints. Based on this positive Phase 2 data, the FDA has granted brepocitinib Breakthrough Therapy Designation for the treatment of CS; initiation of a Phase 3 program in CS expected in the second half of calendar year 2026.

- Enrolled the first subjects in a seamless Phase 2b/3 potentially registrational trial of brepocitinib in lichen planopilaris ("LPP").

- **Anti-FcRn Franchise**

  - Announced Week 16 (end of Period 1) results from the IMVT-1402 trial in difficult-to-treat rheumatoid arthritis ("D2T RA") of ACR20, ACR50 and ACR70 response rates of 72.7%, 54.5% and 35.8%, respectively. Further updates on this program, as well as topline data from the fully enrolled proof-of-concept trial in cutaneous lupus erythematosus ("CLE"), are expected in the second half of calendar year 2026. All other clinical development timelines remain on track for IMVT-1402, including potentially registrational trials in Graves' disease ("GD"), myasthenia gravis ("MG"), chronic inflammatory demyelinating polyneuropathy ("CIDP") and Sjögren's disease ("SjD").

  - Roivant-led Immunovant financing alongside key institutional investors in December 2025 generated gross proceeds to Immunovant of approximately $550 million, extending Immunovant's cash runway to the potential launch of IMVT-1402 in GD.

  - Presented positive six-month off-treatment data from the proof-of-concept Phase 2 clinical trial of batoclimab for the treatment of uncontrolled GD at the American Thyroid Association Annual Meeting. In April 2026, we announced topline results from the two Phase 3 clinical studies evaluating batoclimab for adults with active, moderate-to-severe thyroid eye disease ("TED"), neither of which met the primary endpoint. The safety profile observed in these studies was consistent with prior batoclimab studies. Following these results, we discontinued further development of batoclimab across all indications to focus fully on IMVT-1402. Learnings from the batoclimab program, including clinical data, operational trial experience and relationships with investigators, have been and continue to be leveraged to inform and potentially accelerate the development of IMVT-1402.

- **Mosliciguat**

  - Completed enrollment within one year of first patient dosing in the Phase 2 PHocus study of mosliciguat in 135 patients with pulmonary hypertension associated with interstitial lung disease ("PH-ILD); topline data expected in the second half of calendar year 2026.

- **Patent Infringement Litigation**

  - Announced a $2.25 billion global settlement with Moderna, ending all pending U.S. and international patent-infringement litigation filed by Genevant Sciences GmbH ("Genevant") and Arbutus against Moderna; Moderna to pay Genevant and Arbutus $950 million in July 2026 and an additional $1.3 billion contingent upon resolution of Moderna's Section 1498 appeal favorable to Genevant and Arbutus.

- Claim construction ruling in Genevant and Arbutus's lawsuit against Pfizer and BioNTech in the U.S. District Court for the District of New Jersey for patent infringement in the manufacture and sale of their COVID-19 vaccine was issued in September 2025, construing the disputed claim terms in a manner that Genevant generally considers to be favorable.

Summary of Vant Milestone & Royalty Payments

The following table summarizes select potential future payment obligations from in-licensings for select product candidates.

Vant / Licensor	Product Candidate	Milestones	Royalties
Priovant / Pfizer	Brepocitinib	• Mid-tens-of-millions sales milestone payment if aggregate net sales in a given year exceed a mid-hundreds-of-millions amount	• Tiered sub-teens royalty on net sales
Immunovant / HanAll	Anti-FcRn Franchise	• Up to a maximum of $420M upon the achievement of certain regulatory and sales milestone events	• Tiered mid-single-digits to mid-teens royalty on net sales
Pulmovant / Bayer	Mosliciguat	• Up to a maximum of $280M in development, regulatory and sales milestone events	• Tiered high-single-digits royalty on net sales
Genevant / Arbutus	LNP Technology	—	• Up to 20% of Royalty-Related Receipts[1]

Note: The summaries above do not purport to be complete. Please refer to "—Vant License Agreements & Other Vant Agreements" and the agreements themselves, filed as exhibits to this Annual Report on Form 10-K, for more information on the terms of these agreements.

1. *For information on the settlement agreement resolving patent infringement litigation between Genevant Sciences GmbH, Arbutus Biopharma Corporation, Moderna, Inc. and ModernaTx, Inc., and potential payments related thereto, please refer to Note 5, "Recent Transactions and Developments" of our audited financial statements. See "—Vant License Agreements & Other Vant Agreements" for more information on the terms of the Cross-License Agreement between Genevant and Arbutus and the term "Royalty-Related Receipts."*

Vant Ownership

The following table summarizes our ownership of certain of our subsidiary companies and affiliates as of March 31, 2026.

	Roivant Ownership	
Vant	**Basic[1]**	**Fully Diluted[2]**
Priovant	72%	66%
Immunovant	56% [3]	52% [3]
Pulmovant	97%	90%
Genevant	83%	64%
Covant	94%	91%
Arbutus	20% [3]	19% [3]

Note: In addition to the subsidiary companies and affiliates listed in the table above, Roivant continues to maintain ownership interests in certain other entities as previously disclosed, including Proxima (formerly VantAI), PsiThera (formerly Psivant) and Datavant, as well as the right to receive future milestones and royalties related to the sale of our subsidiary Dermavant to Organon in 2024. The reference to "Genevant" in the table above is to Genevant Sciences Ltd.

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.*

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
Brepocitinib	Priovant	FDA decision on brepocitinib in dermatomyositis	3Q 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 3 trials in non-infectious uveitis	2H 2026
IMVT-1402	Immunovant	Topline data from Phase 2 trial in cutaneous lupus erythematosus	2H 2026
IMVT-1402	Immunovant	Further updates from difficult-to-treat rheumatoid arthritis program	2H 2026
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
Brepocitinib	Priovant	Topline data from Phase 3 trial in cutaneous sarcoidosis	TBC
Brepocitinib	Priovant	Topline data from Phase 2b/3 trial in lichen planopilaris	TBC

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.

Priovant Overview

- **Overview:**
  - Priovant is developing brepocitinib, a potent small molecule inhibitor of JAK1 and TYK2, for the treatment of dermatomyositis ("DM"), non-infectious uveitis ("NIU"), cutaneous sarcoidosis ("CS"), lichen planopilaris ("LPP") and other immune-mediated diseases.

- **Lead program:**
  - Brepocitinib is a potentially first-in-class, orally administered, small molecule inhibitor of JAK1 and TYK2 that suppresses signaling of JAK1- and TYK2-dependent cytokines linked to autoimmune disease, including type I and type II interferon, IL-6, IL-12 and IL-23.

- **Disease overview:**
  - DM is a chronic, immune-mediated disease of the skin and muscles. Patients with DM usually present with a characteristic skin rash and proximal muscle weakness, which may lead to significant functional impairment

and/or disfigurement. Patients with DM are at a substantially increased risk of interstitial lung disease, malignancy and heart failure, contributing to an estimated 5-year mortality rate of 10-40%.

- NIU is an immune-mediated disease of the eye. Patients with NIU usually present with eye inflammation, which can manifest as eye pain, eye redness, light sensitivity, blurred vision, reduced vision and floaters. Patients with NIU are at a substantially increased risk of blindness, contributing to approximately 10% of cases of blindness in the U.S.

- CS is an immune-mediated disease of the skin. CS is the second-most common organ manifestation among sarcoidosis patients and can be disfiguring in cases with significant facial or body surface area involvement. Patients with CS usually present with macules, papules, plaques or nodules. Uncontrolled disease can progress to cartilage and bone destruction and permanent deformity.

- LPP is an immune-mediated disease of the skin. Patients with LPP usually present with redness, scaling and scarring on the scalp that is often accompanied by pain and/or burning, which may lead to generally irreversible hair loss. Patients with LPP are at a substantially increased risk of dermatological malignancies and other severe comorbidities.

- We estimate that there are approximately 70,000 adult DM patients, approximately 400,000 adult NIU patients, including 70,000 to 190,000 adult non-anterior NIU patients, approximately 40,000 adult CS patients and approximately 100,000 adult LPP patients in the U.S.

- **Limitations of current treatments:**

  - Corticosteroids, disease-modifying antirheumatic drugs ("DMARDs") and immunosuppressants, administered alone or in combination, are traditional therapies for patients with DM, NIU, CS and LPP. Many of these therapies are associated with significant toxicities and limited efficacy.

  - For patients with DM who do not respond adequately to traditional therapies, IVIg (OCTAGAM 10%) is an important FDA-approved treatment. However, clinical trial data from the Phase 3 ProDERM study of IVIg in patients with DM and case reports from years of prior off-label use confirm that even with IVIg, many patients with DM continue to suffer from residual disease activity. Moreover, IVIg administration is burdensome, typically requiring several hours of infusion therapy for multiple days each month. IVIg also has a black box warning for serious risks, including thrombosis and kidney failure.

  - For patients with NIU who do not respond adequately to traditional therapies, adalimumab (HUMIRA) administered subcutaneously, is the only FDA-approved modern treatment. NIU patients treated with HUMIRA have failure/relapse rates of approximately 50%, indicating a large unmet need for more efficacious treatment options.

  - Treatment for patients with CS follows a step-up paradigm that mirrors other inflammatory skin disease, including intralesional or high-potency topical steroids, systemic corticosteroids and TNF inhibitors, thalidomide and other off-label agents. There are currently no approved modern therapies for patients with CS.

  - Treatment for patients with LPP follows a step-up paradigm that mirrors other inflammatory skin disease, including intralesional or high-potency topical steroids, topical minoxidil, systemic corticosteroids or ISTs, retinoids and other off-label agents. There are currently no approved modern therapies for patients with LPP.

- **Clinical data:**

  - In the Phase 3 VALOR study of once-daily oral brepocitinib in DM, the 30 mg results demonstrated clinically meaningful and statistically significant improvement compared to placebo on the primary endpoint and all nine key secondary endpoints, including measurements of skin disease, muscle disease, steroid-sparing effect, disability and rapidity of onset. On the primary endpoint, brepocitinib 30 mg achieved a week 52 mean Total Improvement Score (TIS) of 46.5 compared to 31.2 for placebo (p=0.0006), even with nearly twice as many patients coming off background steroids on brepocitinib 30 mg compared to placebo. More than two thirds of brepocitinib 30 mg patients experienced at least a moderate response (TIS≥40), and nearly half experienced a major response (TIS≥60). The safety profile was consistent with previous clinical trials of brepocitinib and adverse events of special interested (AESIs) did not occur with greater frequency in the brepocitinib 30 mg arm than the placebo arm.

  - Brepocitinib has been evaluated in eight positive completed Phase 2 studies in immune-mediated diseases (alopecia areata, psoriatic arthritis, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, Crohn's disease, non-infectious uveitis and cutaneous sarcoidosis). In the seven of these that were placebo-controlled studies, treatment with brepocitinib was associated with statistically significant and clinically meaningful efficacy. In the Phase 2 NEPTUNE proof-of-concept study, brepocitinib demonstrated the best time to treatment failure observed to date among active NIU studies measuring this registrational endpoint.

Study Population	N[1]	Brepocitinib Dose	Primary Endpoint Result	Statistical Significance
Alopecia Areata	94[2]	30 mg once daily[3]	49.18 placebo-adjusted CFB in SALT Score at week 24	P < 0.0001[4]
Psoriatic Arthritis	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	P = 0.0197
Ulcerative Colitis	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	P = 0.0005
Plaque Psoriasis	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI score at week 12	P < 0.0001
Hidradenitis Suppurativa	100	45 mg once daily[5]	18.7% placebo-adjusted HiSCR Rate at week 16	P = 0.0298[4]
Crohn's Disease	151	60 mg once daily[6]	21.4% placebo-adjusted SES-CD 50 Rate at week 12	P = 0.0012[4]
Non-infectious Uveitis	26	45 mg once daily	29.4% Treatment Failure Rate at week 24	
Cutaneous Sarcoidosis	31	45 mg once daily	21.6 placebo-adjusted CFB in CSAMI-A at week 16	P < 0.0001

1. *Overall study N represents patients randomized to all brepocitinib dose levels or placebo and excludes patients randomized to other agents.*
2. *Includes patients from initial 24-week study period only.*
3. *60 mg once daily for 4 weeks followed by 30 mg once daily for 20 weeks.*
4. *One-sided p-value (pre-specified statistical analysis).*
5. *Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study.*
6. *Brepocitinib 60 mg once daily was the only brepocitinib dose evaluated in the induction period of this study.*

The non-infectious uveitis and cutaneous sarcoidosis studies were conducted by Priovant; all other brepocitinib studies shown in the table above were conducted by Pfizer.

ACR20: American College of Rheumatology 20% Improvement; RR: Response Rate; CFB: Change From Baseline; PASI: Psoriasis Area and Severity Index; SALT: Severity of Alopecia Tool; HiSCR: Hidradenitis Suppurativa Clinical Response; SES-CD: Simple Endoscopic Score for Crohn's Disease; CSAMI-A: Cutaneous Sarcoidosis Activity and Morphology Instrument-Activity Score

- In the Phase 2 NEPTUNE study of once-daily oral brepocitinib in NIU, the 45 mg results represented the best Treatment Failure rates observed to date among active NIU studies measuring this endpoint. On the pre-specified primary efficacy endpoint of Treatment Failure at week 24, a composite endpoint comprising multiple measures of ocular inflammation and visual acuity, as well as discontinuation due to intercurrent events or initiation of rescue therapy, 29% of subjects receiving brepocitinib 45 mg and 44% of subjects receiving brepocitinib 15 mg met Treatment Failure criteria (lower failure rates reflect greater treatment benefit). All secondary efficacy endpoints were also positive and dose responsive, including measurements of potential benefit on prevention and treatment of uveitic macular edema. 52-Week data from the same study confirmed sustained treatment effect and tolerability. Brepocitinib was generally safe and well tolerated in the study, with no new safety or tolerability signals identified.

- In the Phase 2 BEACON study of once-daily oral brepocitinib in CS, the 45 mg arm demonstrated significant improvement in cutaneous sarcoidosis disease activity, achieving a 22.3-point improvement in mean CSAMI-A at Week 16 versus a 0.7-point improvement in placebo (Δ21.6, $P<0.0001$). Brepocitinib demonstrated rapid, deep and sustained improvements across all other efficacy endpoints measured with consistent safety profile.

- Brepocitinib was studied in patients with LPP in a placebo-controlled investigator-initiated trial at the Icahn School of Medicine. Brepocitinib significantly reduced the Lichen Planopilaris Activity Index (LPPAI) score from baseline. Brepocitinib was well tolerated and maintained a favorable safety profile in the investigator-initiated trial.

- Brepocitinib's safety database includes over 2,000 exposed participants evaluated in completed and ongoing clinical studies. In these studies, brepocitinib was generally safe and well tolerated, and rates of JAK class treatment-emergent adverse events ("TEAEs") of interest were comparable to those observed in the development programs of approved JAK inhibitors. Collectively, these data suggest a safety profile that is similar to those of approved JAK inhibitors.

- **Development plan and upcoming milestones:**

  - Priovant's filing for use of brepocitinib in DM has been accepted by the FDA with Priority Review with a PDUFA target action date in the third quarter of calendar year 2026. Priovant expects to launch brepocitinib in DM by the end of September 2026 following FDA approval.

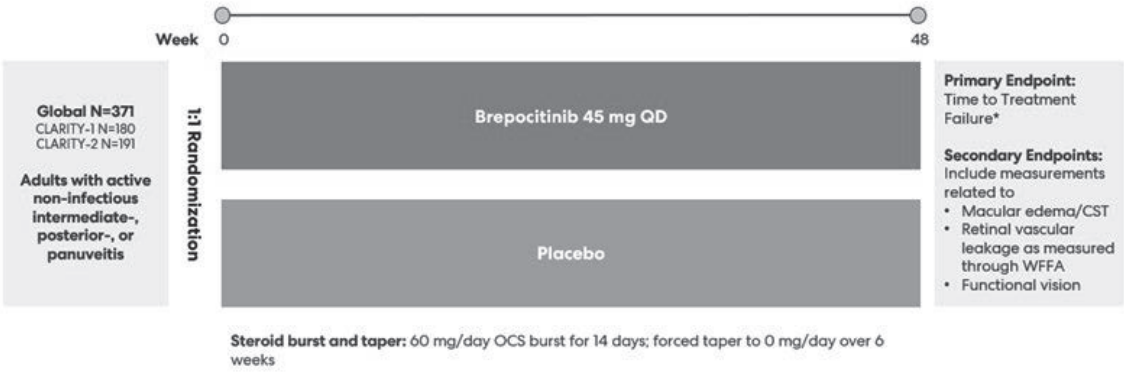
  - Priovant has fully enrolled a Phase 3 program in non-infectious uveitis; topline data are expected in the second half of calendar year 2026.

  - Priovant initiated a Phase 2b/3 program in lichen planopilaris in the first half of calendar year 2026.

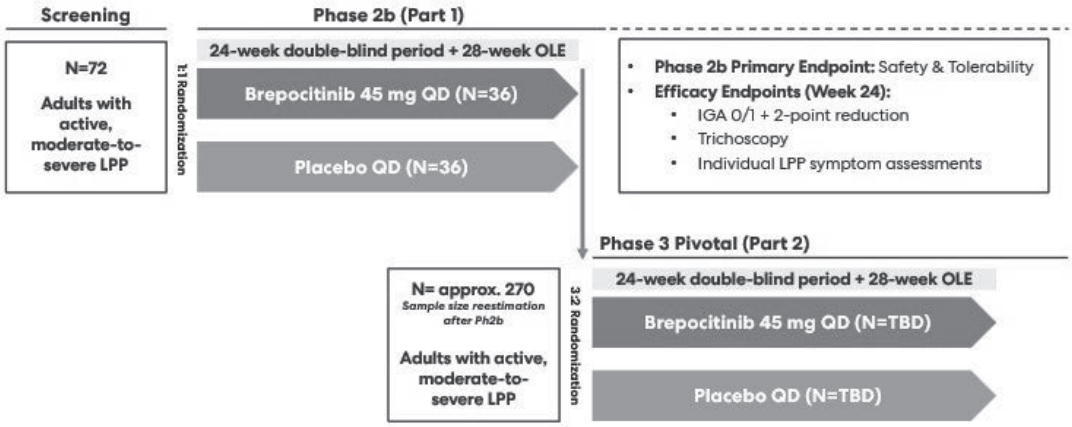
  - Priovant received Breakthrough Therapy Designation for brepocitinib for the treatment of cutaneous sarcoidosis and plans to initiate a Phase 3 program in the second half of calendar year 2026.

The below schematics show the trial designs for the ongoing brepocitinib trials:

NIU Phase 3 Trial Design



LPP Phase 2b/3 Trial Design



- **<u>Roivant ownership</u>:**

  - As of March 31, 2026, we owned 72% of the issued and outstanding shares of Priovant (or 66% on a fully diluted basis).

<u>Immunovant Overview</u>

- **<u>Overview</u>:**

  - Immunovant is developing IMVT-1402, a potentially best-in-class inhibitor of the neonatal fragment crystallizable receptor ("FcRn"), for the treatment of IgG-mediated autoimmune diseases, including Graves' disease ("GD"), difficult-to-treat rheumatoid arthritis ("D2T RA"), Sjögren's disease ("SjD"), myasthenia gravis ("MG"), chronic inflammatory demyelinating polyneuropathy ("CIDP") and cutaneous lupus erythematosus ("CLE").

  - IMVT-1402 has been assigned the nonproprietary name imeroprubart on the World Health Organization's Recommended International Nonproprietary Names List 93, which has also been approved by the U.S. Adopted Names Council.

- **Lead program:**

  - IMVT-1402 is a fully human monoclonal antibody that inhibits FcRn and has shown deep, dose-dependent IgG reductions in a Phase 1 clinical trial in healthy adults. We expect to be able to reach approximately 80% IgG reductions with continued weekly dosing of 600 mg of IMVT-1402, offering deeper IgG reductions than observed with other competitor anti-FcRn programs, therefore representing a potential best-in-class opportunity. There has been consistent evidence observed across the class in over eight indications in Phase 2 and 3 trials with FcRn inhibitors that has indicated that deeper IgG reductions correlate with meaningful improvements in clinical outcomes, which has been further validated by data generated with our first-generation anti-FcRn, batoclimab, in our own Phase 2 and 3 studies. IMVT-1402 offers a potentially best-in-class profile, with potentially best-in-class efficacy given its potential to achieve best-in-class IgG reductions, a favorable route of administration with a simple subcutaneous auto-injector and potentially favorable safety profile.

  - IMVT-1402 is being developed in several indications representing potential first-in-class and best-in-class opportunities, including GD, D2T RA and CLE, and we plan to leverage the potentially best-in-class profile of IMVT-1402 in indications where the anti-FcRn mechanism has already established a commercial presence, such as MG and CIDP. We plan to be laser-focused on clinical execution to maintain our head start in the indications listed above and to be nearly-first and best-in-class for indications such as SjD where we are close from a timing perspective to in-class competition and expect a differentiated clinical profile.

- **Disease overview:**

  Endocrine Diseases

  - Graves' disease is an autoimmune disease that affects the thyroid gland. Patients with Graves' disease develop IgG autoantibodies that bind to the thyroid-stimulating hormone receptor ("TSHR") present on the thyroid gland, which induces increased and uncontrolled secretion of thyroid hormones, resulting in hyperthyroidism. A conservative analysis of Inovalon claims data estimates that the prevalence of Graves' patients is approximately 880,000 in the U.S., and further analysis suggests that there are approximately 330,000 patients who have relapsed on ATDs and who have opted not to pursue ablation.

  Rheumatology Diseases

  - Rheumatoid arthritis is a chronic progressive autoimmune disease that causes inflammation in the joints and surrounding tissues. Inadequate control of the joint inflammation associated with rheumatoid arthritis may result in irreversible joint erosions. The estimated prevalence of patients treated with biologic or targeted synthetic disease modifying anti-rheumatic drugs ("DMARDs") in the U.S. is approximately 820,000, approximately 15% of which had an inadequate response to two or more such prior advanced DMARD mechanisms. The rheumatoid arthritis described in this subset of patients is sometimes referred to as difficult-to-treat ("D2T"), refractory or multi-advanced mechanism failure rheumatoid arthritis. Of those, approximately 70% are autoantibody positive, representing approximately 85,000 patients with significant unmet medical need in the U.S.

  - SjD is a chronic autoimmune disease characterized by lymphocytic infiltration of the salivary and lacrimal glands. Autoantibodies including anti-Ro/SSA and anti-La/SSB have been detected in approximately 50-70% of patients with primary SjD and play crucial roles in both the diagnosis and prognosis of the disease. The estimated prevalence of primary SjD is approximately 290,000 in the United States. It is estimated that up to 30% of primary SjD patients have moderate-to-severe disease with anti-Ro/SSA antibodies, representing approximately 90,000 SjD patients with significant unmet medical need in the U.S.

  Dermatological Diseases

  - CLE is a rare, chronic skin disease characterized by skin-specific disease activity, inflammation and eventually damage. IgG autoantibodies and immune complexes are observed to play a critical role in CLE disease pathophysiology. Subacute Cutaneous LE ("SCLE") and Chronic Cutaneous LE ("CCLE") are subtypes of CLE with distinct skin presentation and clinical course and high unmet medical need. The estimated prevalence of SCLE and CCLE is approximately 153,000 in the U.S. Approximately 50% of these

SCLE and CCLE patients do not adequately respond to first-line therapies representing approximately 75,000 patients with significant unmet medical need in the U.S.

Neurological Diseases

- MG is a rare, chronic autoimmune disorder characterized by weakness and fatigue of voluntary muscles. MG patients develop autoantibodies that lead to an immunological attack on critical signaling receptor proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. The prevalence of MG is estimated to be approximately 116,000 cases in the U.S. with 35% of patients not well-controlled on the current standard of care, representing approximately 41,000 patients with significant unmet medical need in the U.S. The majority of these patients demonstrate elevated serum levels of acetylcholine receptor ("AChR") antibodies.

- CIDP is believed to be an immune-mediated neuropathy characterized by demyelination of peripheral nerves and nerve roots that is driven by pathologic, autoreactive IgG antibodies. The estimated prevalence of CIDP is approximately 77,000 patients in the U.S., with approximately 25% inadequately controlled on treatment, representing approximately 19,000 patients with significant unmet medical need in the U.S.

- **Limitations of current treatments:**

  - For many IgG-mediated autoimmune diseases, early-stage disease control involves corticosteroids and immunosuppressants, later progressing to intravenous immunoglobulin ("IVIg") or plasma exchange ("PLEX"). Immunomodulatory therapies are frequently associated with significant potential risks, including the possibility of malignancy and infection. These approaches are generally limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

Endocrine Diseases

- GD: There are three options available for GD: surgery, RAI and oral antithyroid drugs ("ATDs"). Rates of surgery and RAI have declined significantly in the U.S. in recent years due to associated severe potential complications. While ATDs are considered generally safe, their chronic use can be associated with hepatotoxicity, pancreatitis and bone marrow toxicity, and up to 25-30% of GD patients remain uncontrolled on ATDs.

Rheumatology Diseases

- D2T RA: Currently available treatments used to help control joint inflammation, damage and other manifestations of rheumatoid arthritis include a variety of conventional oral, targeted synthetic and biologic DMARDs. D2T RA patients continue to experience active disease despite undergoing multiple lines of therapy with different mechanisms of action. For these patients, therapeutic options remain very limited, highlighting a persistent and critical unmet medical need. The European Alliance of Associations for Rheumatology ("EULAR") has defined this rheumatoid arthritis subset in the clinical setting as D2T-RA and provided points to consider in its management. Nevertheless, innovative strategies and novel therapeutic targets are needed to improve outcomes and quality of life for this patient population.

- SjD: No therapies have been approved specifically for the treatment of SjD. Therapeutic approaches for SjD include local agents for oral and ocular dryness as well as systemic treatments to address organ manifestations. There is a significant need for the development of novel treatments that target the underlying pathophysiological mechanism of this disease.

Dermatological Diseases

- CLE: First-line therapies for CLE include photoprotection, topical steroids and broad-spectrum therapies (i.e. DMARDs, antimalarials and corticosteroids) followed by IVIG or off-label biologics. It is estimated that approximately 50% of patients are not optimally managed with or without topical steroids due to insufficient response, relapse or risk of retinopathy following first-line antimalarials.

Neurological Diseases

- MG: Early-stage MG is symptomatically treated with acetylcholinesterase inhibitors. As the disease progresses, patients are typically treated with immunosuppressive agents such as glucocorticoids, azathioprine, mycophenolate mofetil and cyclosporine. Recently approved novel mechanism of action therapies for MG include FcRn inhibitors, which generally reduced IgG by 60-70% in their Phase 3 trials at approved doses, and complement inhibitors. We believe there is unmet need for a higher efficacy benefit and a more durable clinical responses for patients with MG.

- CIDP: IVIg, corticosteroids and PLEX are first-line therapies in the treatment of CIDP. An anti-FcRn inhibitor has also been approved for the treatment of CIDP; however, we believe there is still meaningful room to improve on efficacy.

- **Clinical data:**

  - In September and November 2023, we announced results from a Phase 1 clinical trial in healthy adults dosed with IMVT-1402. In the study's 300 mg multiple-ascending dose ("MAD") cohort, a statistically significant reduction of 63% from baseline in mean total IgG levels was observed after four weekly 300 mg subcutaneous doses of IMVT-1402. In the 600 mg MAD cohort, we observed a statistically significant reduction of 74% from baseline in mean total IgG levels after four weekly 600 mg subcutaneous doses of IMVT-1402. No or minimal reductions in albumin and no or minimal increases in LDL cholesterol levels were observed in healthy adults administered IMVT-1402 in either dose cohort; the changes in albumin and LDL cholesterol were similar to those observed with placebo administration. Across all doses evaluated, treatment with IMVT-1402 was generally well tolerated, with only mild or moderate treatment-emergent adverse events observed.

  - In April 2025, we presented observations from a proof-of-principle case study evaluating IMVT-1402 in an SCLE patient over a period of 12 weeks. The participant in the case study had a baseline Cutaneous Lupus Erythematosus Disease area and Severity Index activity ("CLASI-A") score at screening of 36, which falls into the severe range of the clinical scale. The participant received open-label weekly treatment with 600 mg of IMVT-1402 for 12 weeks and saw significant clinical improvement in both skin lesions and alopecia. By week 12, the participant had a greater than 60% reduction in CLASI-A score to 13. A 5-point reduction in CLASI-A is considered clinically meaningful and this participant improved by 23 points by week 12. The participant also achieved approximately 78% total IgG reduction from baseline by week 12. A second patient dosed in this study also showed significant clinical improvement, with a CLASI-A score of 18 at screening reduced to 8 by week 12 of QW dosing, a >50% improvement.

  - In September 2025, we presented six-month off-treatment data in uncontrolled GD patients treated with batoclimab for 24 weeks at the 2025 Annual Meeting of the American Thyroid Association (ATA). At completion of the follow-up period at Week 48 (i.e., subjects off-treatment for 24 weeks), approximately 80% (17/21) of those subjects maintained T3/T4 values ≤ upper limit of normal ("ULN"), suggestive of strong durability of the response observed at Week 24 as evaluated at approximately six months off treatment at Week 48. Of these 17 subjects, approximately 50% (8/17) were ATD-free and an additional approximately 30% (5/17) were on ATD doses of 2.5 mg/day at six months off batoclimab treatment. Total IgG and TSHR antibodies ("TRAb") levels declined through Week 24, consistent with previous observations, and while total IgG rebounded after treatment ended, pathogenic TRAb levels remained suppressed at Week 48. Safety and tolerability were observed to be consistent with prior batoclimab studies. This study is now completed, with its data suggesting the potential of FcRn inhibition for the treatment of GD by modifying the underlying disease pathology, which is driven by stimulating TRAb. As such, GD is a key strategic priority for our development of IMVT-1402.

  - In April 2026, we announced top-line results from two Phase 3 clinical studies evaluating batoclimab as an investigational treatment for adults with active, moderate-to-severe thyroid eye disease ("TED"), neither of which met the primary endpoint. The safety profile observed in these studies was consistent with prior batoclimab studies, with no new safety signals identified. Following these results, we made a decision to discontinue further development of batoclimab across all indications to focus fully on IMVT-1402. Learnings from the batoclimab program, including clinical data, operational trial experience and relationships with investigators, have been and continue to be leveraged to inform the development of IMVT-1402.

- In May 2026, we announced Week 16 (end of Period 1) results from the currently ongoing potentially registrational trial of IMVT-1402 in D2T RA. At the completion of Period 1, 165 of the 170 patients were evaluable for ACR20 response. Of these patients, 86.7% (143/165) had failed two prior mechanisms of advanced therapies, and the mean time since diagnosis was 12.8 years. Baseline disease activity was high, with mean counts of 24.2 tender joints, 16.7 swollen joints and a DAS28-CRP score of 6.1. At Week 16, the observed ACR20, ACR50 and ACR70 response rates were 72.7%, 54.5% and 35.8%, respectively; participants who discontinued prior to Week 16 were imputed as non-responders. Among the subset of participants who had failed at least a JAK inhibitor and an anti-TNF inhibitor (N=107), the Week 16 observed ACR20, ACR50 and ACR70 response rates were 72.0%, 53.3% and 37.4%, respectively. IMVT-1402 was observed to be safe and well-tolerated in Period 1, and no new drug-related safety signals were identified.

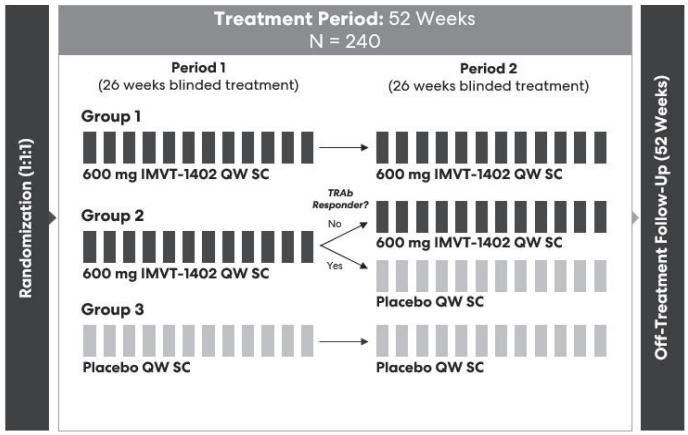
- **Development plan and upcoming milestones:**

  - We are currently progressing a broad set of programs for IMVT-1402, and have ongoing studies in six indications, including potentially registrational trials in GD, D2T RA, MG, CIDP and SjD, and a proof-of-concept trial in CLE. All studies evaluating IMVT-1402 are being conducted using the intended commercial drug formulation and delivery device, the YpsoMate® autoinjector developed by Ypsomed AG, which is utilized by multiple approved products.

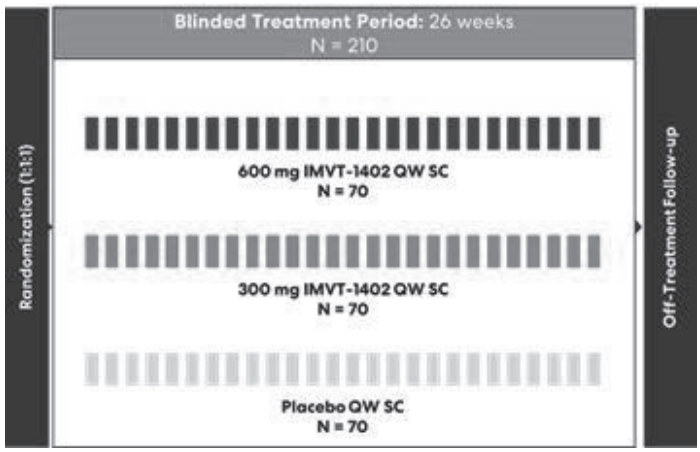
  - We have commenced discussions with HanAll regarding the future disposition of batoclimab, including the potential return to HanAll of certain rights for batoclimab. In April 2026, we notified HanAll of our decision to indefinitely delay further development of batoclimab and focus our resources fully on IMVT-1402. Under the HanAll Agreement, we retain final decision-making authority over development and regulatory matters for licensed products in the HanAll Licensed Territory (as defined below), and we believe we have satisfied our obligations under the HanAll Agreement (as defined below), including with respect to batoclimab. HanAll may disagree with our interpretation of the agreement or our actions thereunder, and we may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation.

The below schematics show the trial designs for the select IMVT-1402 and batoclimab trials:

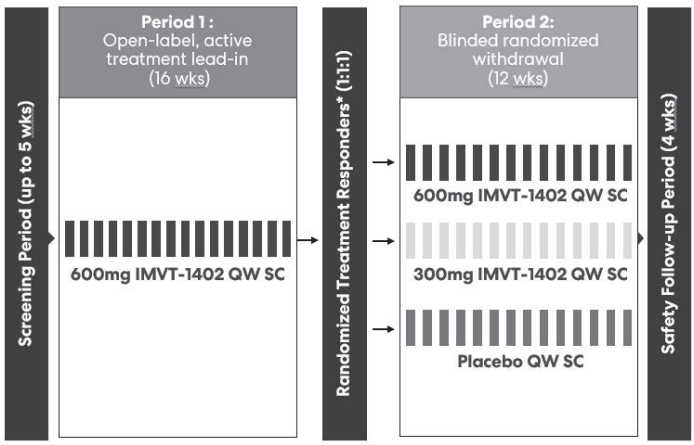
First IMVT-1402 GD Potentially Registrational Trial Design



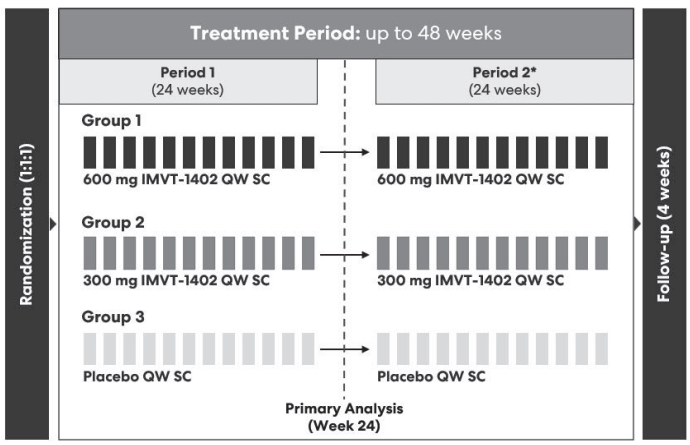
Second IMVT-1402 GD Potentially Registrational Trial Design



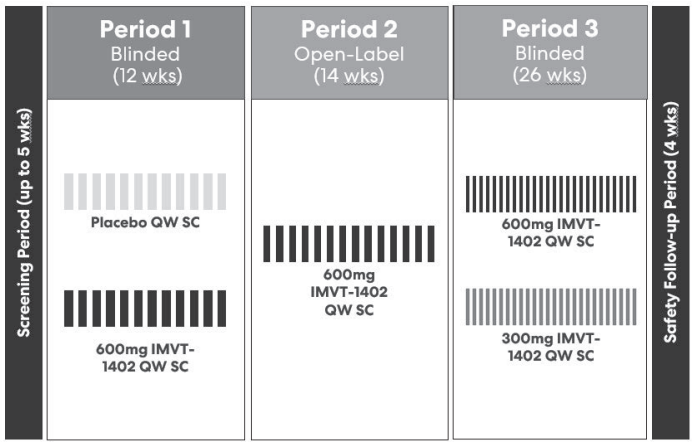
IMVT-1402 D2T RA Potentially Registrational Trial Design



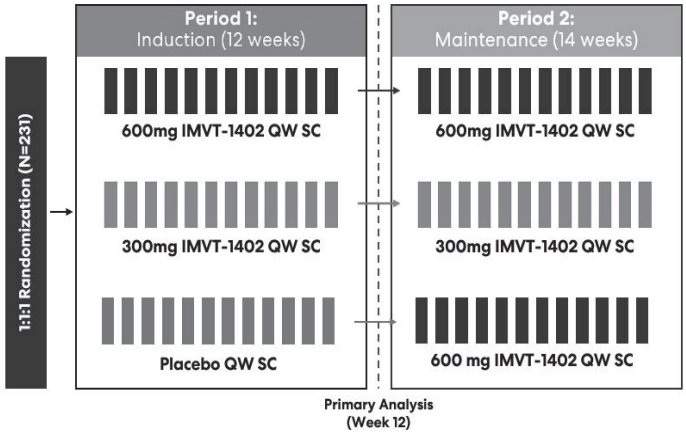
First IMVT-1402 SjD Potentially Registrational Trial Design



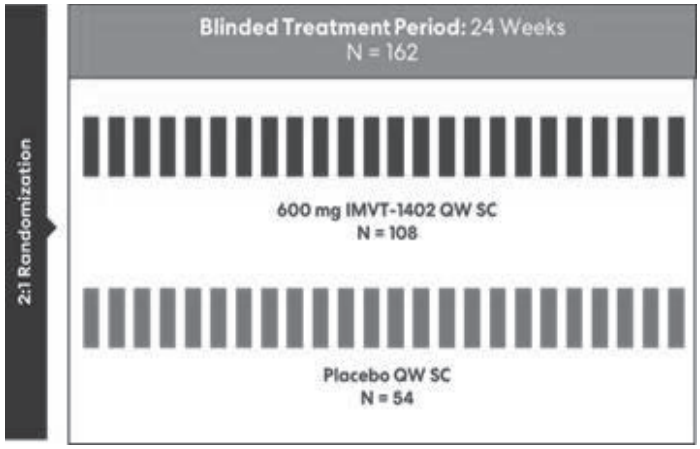
IMVT-1402 CLE Proof-of-Concept Trial Design



IMVT-1402 MG Potentially Registrational Trial Design



IMVT-1402 CIDP Potentially Registrational Trial Design



- **<u>Roivant ownership</u>:**
  - As of March 31, 2026, we owned 56% of the issued and outstanding shares of Immunovant (or 52% on a fully diluted basis).

Pulmovant Overview

- **Overview:**

  - Pulmovant is developing mosliciguat for the treatment of pulmonary hypertension associated with interstitial lung disease ("PH-ILD") and potentially other cardiopulmonary diseases.

- **Lead program:**

  - Mosliciguat is a once-daily, inhaled sGC activator with the potential to be first-in-class and best-in-category. Mosliciguat is currently being developed in PH-ILD, which is a large, well-validated market with only two approved treatments (both inhaled treprostnil), which are limited to the U.S. and a small number of other countries. In a dose escalation, proof-of-concept Phase 1b trial that assessed the efficacy, safety, tolerability and pharmacokinetics of mosliciguat following single dose inhaled administration in pulmonary hypertension ("PH") patients, clinically meaningful mean-max reductions in pulmonary vascular resistance ("PVR") of up to approximately 38% were observed and were sustained over the study period. These reductions represent some of the highest reductions seen in PH trials to date.

- **Disease overview:**

  - Pulmonary hypertension is a heterogeneous and highly morbid disease that can occur clinically as an isolated disorder or as a complication associated with other diseases and conditions. PH leads to increased blood pressure in the arteries of the lung and right side of the heart. WHO Group 3 PH is comprised of patients with various types of concomitant, chronic lung diseases and represent approximately 40% of all PH patients, including PH-ILD and PH-COPD. Features of PH-ILD include progressive fibrosis and hypoxemia, lung function decline resulting in respiratory failure, pulmonary hypertension and right ventricular failure with progressive symptom worsening and early mortality.

  - PH-ILD is estimated to affect up to 200,000 patients in the U.S. and E.U with median survival of approximately two to three years after PH diagnosis.

  - PH-ILD has been historically underdiagnosed given the diverse nature of the underlying diseases with limited treatment options. The use of right heart catheterization ("RHC") and other diagnostic modalities to confirm definitive diagnosis is expected to grow with the availability of approved PH-ILD treatments, thus expanding the market for mosliciguat. Among the ILD patients under the care of 25 physicians surveyed in 2021, 29% had a diagnosis of PH-ILD that was confirmed by RHC, while another 30% had suspected PH-ILD but had not received a confirmed diagnosis via RHC. These physicians also indicated they would increase the percentage of PH-ILD patients on whom they perform RHC by a factor of approximately 1.5x with the availability of other PH therapies.

- **Limitations of current treatments:**

  - The treatment of PH-ILD patients is based on an individualized and holistic approach. Patients with mildly elevated PVR or mean pulmonary arterial pressure ("mPAP") can mainly be treated for their underlying lung disease which includes antifibrotic medications and immunosuppressants. Patients whose PVR and mPAP are significantly elevated in the context of their fibrotic lung disease should be treated with PH-specific treatments. However, Tyvaso and Yutrepia (inhaled treprostinils) are the only approved treatments for PH-ILD patients in the U.S., with Tyvaso also available in a small number of other countries. Most patients outside of these geographies, including in the E.U., have no approved options. They can potentially be considered on a case-by-case basis for off-label treatment with pulmonary arterial hypertension ("PAH")-specific drugs not approved for PH-ILD.

  - Even with Tyvaso's and Yutrepia's availability, there is still substantial unmet need for new drugs for PH-ILD with different mechanisms of action ("MoA") and improved efficacy, tolerability and delivery. Patients on Tyvaso have been observed to have side effects impeding them from realizing optimal benefit at the maximum dose level. On-target adverse events such as cough, headache, throat irritation, nausea and flushing may cause tolerability issues for patients on Tyvaso and on Yutrepia. The same tolerability concerns have largely relegated prostacyclin usage in PAH to high-risk and advanced disease patients. We believe there is a

significant opportunity for an agent like mosliciguat, given its MoA and inhaled, once per day, single capsule administration as well as potentially improved efficacy and tolerability compared to Tyvaso and Yutrepia, to be used as initial therapy in place of inhaled treprostinil or as an add-on treatment to inhaled treprostinil.

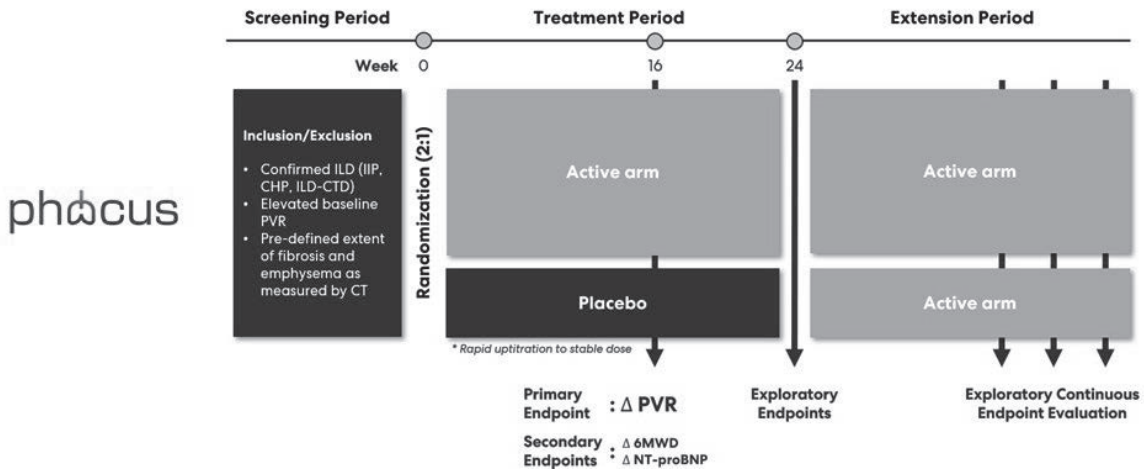
- **Clinical data:**

  - Phase 1b data from the non-randomized, open-label ATMOS study with a single inhaled dose of mosliciguat showed dose-dependent mean-max reductions in PVR of up to 38% in Group 1 (PAH) and Group 4 (CTEPH) PH patients, and demonstrated a favorable safety profile with no clinically relevant systemic side effects, such as heart rate and blood pressure changes. Trials of other agents in PAH have shown that reductions in PVR are potential predictors of success on clinical outcomes such as 6-minute walk distance.

- **Development plan and upcoming milestones:**

  - We have completed enrollment in a global Phase 2 trial to evaluate the safety and efficacy of mosliciguat in PH-ILD, with data expected in the second half of calendar year 2026. We are also actively enrolling a separate, open-label Phase 2 proof-of-concept trial to evaluate the safety and tolerability of mosliciguat in combination with inhaled treprostinil in PH-ILD.

Mosliciguat Phase 2 PHocus trial in PH-ILD



- **Roivant ownership:**

  - As of March 31, 2026, we owned 97% of the issued and outstanding common shares of Pulmovant (or 90% on a fully diluted basis).

Genevant Overview

For purposes of this "Genevant Overview" section, references to Genevant are to Genevant Sciences Ltd. and its consolidated subsidiaries.

- **Overview:**

  - Genevant is a technology-focused nucleic acid delivery and development company with two delivery platforms—a lipid nanoparticle ("LNP") platform and a ligand conjugate platform—an expansive intellectual property portfolio and deep scientific expertise, currently focused on partnering with other pharmaceutical or biotechnology companies to enable the development of nucleic acid therapeutics for unmet medical needs.

- **Delivery platforms and patent portfolio:**

  - Genevant has two delivery platforms: LNP and ligand conjugate.

- *LNP platform*:

  - Technology used in the first systemic RNA-LNP product to receive FDA-approval, Alnylam's Onpattro (patisiran) for the treatment of polyneuropathy caused by hereditary ATTR amyloidosis.
  - Outperformed all third-party formulations tested in a head-to-head *in vivo* ionizable lipid study assessing LNP potency and immune stimulation.
  - Clinically validated for hepatocyte and vaccine applications and in various stages of development for other traditionally hard-to-reach tissues and cell types, including T-cells, immune cells, stellate cells, lung, eye, and central nervous system.
  - More than 700 issued patents and pending patent applications worldwide as of March 31, 2026, including patents directed to:
    - lipid structures, including cationic and PEG-lipids
    - particle compositions, including ranges of lipid ratios for nucleic acid-containing particles
    - nucleic acid-containing particles with certain structural characteristics
    - mRNA-containing LNP formulations
    - various manufacturing process aspects

- *Ligand conjugate platform*:

  - Novel GalNAc ligands with clinical validation from imdusiran, an siRNA currently in Phase 2 clinical development by Arbutus Biopharma for the treatment of chronic hepatitis B (cHBV).
  - In preclinical head-to-head testing, Genevant's GalNAc ligands demonstrated equal or better preclinical potency, assessed by duration and magnitude of knockdown, compared to a current industry benchmark.

- **Collaboration-based business model:**

  - Genevant seeks to partner with other pharmaceutical or biotechnology companies in the development of RNA therapeutics, crafting mutually beneficial collaborations that allow collaboration partners to access its innovative technologies while providing Genevant the opportunity to leverage its expertise to expand the technology and its therapeutic application.

  - Genevant uses its expertise in the delivery of nucleic acid therapeutics to develop optimal delivery systems for its collaborators' identified payloads.

  - Genevant's collaboration-based business model is to seek upfront payments, R&D reimbursements, milestones and royalties or profit sharing upon success, while also retaining certain rights in the delivery-related intellectual property developed in the context of the collaboration for potential use or out-licensing.

  - Some current collaboration partners include Editas Medicine, Epitopea, Mammoth Biotechnologies and Repair Biotechnologies.

- **Clinical and preclinical data:**

  - Genevant LNP technology has been in clinical trials of over a dozen distinct product candidates, representing thousands of subjects of clinical experience.

  - In a head-to-head study in mice comparing multiple LNP formulations which varied only the key ionizable lipid, Genevant's formulation outperformed all third-party formulations tested. Genevant's formulation showed superior potency and tolerability (based on an assessment of immune stimulation) relative to others.

  - Genevant LNP technology is included in the first systemic RNA-LNP product to receive FDA-approval, Alnylam's Onpattro (patisiran) for the treatment of polyneuropathy caused by hereditary ATTR amyloidosis.

- **IP litigation:**

  - In March 2026, Genevant Sciences GmbH ("GSG"), and, solely for specified purposes, Genevant's parent company Genevant Sciences Ltd., and Arbutus entered into a $2.25 billion global settlement with Moderna to

resolve all patent infringement litigation and patent revocation proceedings involving Moderna and its affiliates pending in the U.S. and internationally. As a part of the settlement, Moderna has agreed to pay GSG and Arbutus $950 million in or before July 2026 and an additional $1.3 billion contingent upon a ruling in Moderna's §1498 Appeal favorable to GSG and Arbutus. Additionally, as a part of this settlement, GSG granted Moderna a global non-exclusive license to LNP delivery technology for infectious disease applications and a covenant not to sue with respect to certain of GSG's and Arbutus' patents and Moderna products.

- In April 2023, GSG and Arbutus jointly filed a complaint against Pfizer and BioNTech in the U.S. District Court for the District of New Jersey asserting infringement of five patents. In September 2025,the Court issued a claims construction ruling construing the disputed claim terms in a manner that GSG generally considers to be favorable. Further scheduling in the litigation remains pending.

- **Roivant ownership:**

  - As of March 31, 2026, we owned 83% of the issued and outstanding common shares of Genevant (or 64% on a fully diluted basis).

Vant License Agreements & Other Vant Agreements

Priovant

License and Collaboration Agreement with Pfizer, Inc.

In September 2021, our subsidiary Priovant Therapeutics, Inc. ("Priovant") entered into a license and collaboration agreement with Pfizer (the "Pfizer-Priovant License Agreement"). Pursuant to the Pfizer-Priovant License Agreement, Pfizer granted Priovant (i) an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and (ii) a non-exclusive, worldwide, sublicensable, royalty-bearing license under certain know-how, in each case, to develop, manufacture and commercialize brepocitinib and TYK2 compounds and products incorporating such compounds for all human and animal uses. In exchange for Pfizer's inventory of these compounds, Priovant paid Pfizer $10.0 million. Priovant also granted back to Pfizer (i) an exclusive, sublicensable, royalty-bearing license under certain patents and (ii) a non-exclusive, sublicensable, royalty-bearing license under certain know-how, in each case, to commercialize (x) brepocitinib and products incorporating such compound outside of the U.S. and Japan, and (y) TYK2 compounds and products incorporating such compounds outside of the U.S., in each case for all human and animal uses.

Priovant is obligated to pay Pfizer a mid tens-of-millions sales milestone payment if aggregate net sales of its licensed products in Priovant's territory in a given year exceed a mid hundreds-of-millions amount. Pfizer is obligated to pay Priovant a low tens-of-millions milestone payment if aggregate net sales of its licensed products outside of Priovant's territory in a given year exceed a mid hundreds-of-millions amount.

Priovant is obligated to pay Pfizer a tiered, sub-teens royalty on aggregate net sales of its licensed products in Priovant's territory. Pfizer is obligated to pay Priovant a tiered high single-digit to sub-teens royalty on aggregate net sales of its licensed products outside of Priovant's territory. Each of Priovant's and Pfizer's royalty obligations apply on a product-by-product and country-by-country basis and end upon the expiration of a customary royalty term, which is the latest of (a) a certain amount of years following the first commercial sale of the applicable product in the applicable country, (b) the date on which the regulatory exclusivity provided by the applicable government authority for the applicable product in that country expires and (c) the date upon which the use, sale, offer for sale or importation of such product in such country would no longer be covered by a valid claim of a licensed product right. Either party may terminate the Pfizer-Priovant License Agreement for the other party's uncured breach and Priovant has the right to terminate for convenience.

Immunovant

License Agreement with HanAll Biopharma Co., Ltd.

In December 2017, our wholly owned subsidiary, Roivant Sciences GmbH ("RSG"), entered into a license agreement with HanAll Biopharma Co., Ltd. ("HanAll") (the "HanAll Agreement"). Under the HanAll Agreement, RSG received (1) the non-exclusive right to manufacture and (2) the exclusive, royalty-bearing right to develop, import, use and

commercialize the antibody referred to as batoclimab and certain back-up and next-generation antibodies (including IMVT-1402), and products containing such antibodies in the U.S., Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America (the "HanAll Licensed Territory"). With respect to these licenses, RSG also received the right to grant a sublicense, with prior written notice to HanAll of such sublicense, to: (1) a third party in any country in the HanAll Licensed Territory outside of the U.S. and E.U.; (2) an affiliate of RSG in any country in the HanAll Licensed Territory; and (3) a third party in the U.S. and E.U. only after submission of a biologics license application ("BLA") in the U.S. or a Marketing Authorization Application in the E.U. Pursuant to the HanAll Agreement, RSG granted to HanAll an exclusive, royalty-free license under certain RSG patents, know-how and other intellectual property controlled by RSG relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the HanAll Licensed Territory. HanAll also reserves the right to conduct discovery or research activities with the batoclimab antibody, and certain back-up and next-generation antibodies (including IMVT-1402), with or through a contract research organization or service provider in the HanAll Licensed Territory.

In December 2018, Immunovant Sciences GmbH, ("ISG") obtained and assumed all of the rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1402 and batoclimab in the HanAll Licensed Territory, pursuant to an assignment and assumption agreement between RSG and ISG, for an aggregate purchase price of $37.8 million. In January 2026, Immunovant completed an internal reorganization and transfer of intellectual property rights related to its product candidates between two wholly-owned subsidiaries of Immunovant. Ownership and rights to such intellectual property remain with Immunovant and its subsidiaries.

Pursuant to the HanAll Agreement, ISG will be responsible for future contingent payments and royalties, including up to an aggregate of $420.0 million upon the achievement of certain regulatory and sales milestone events. ISG is also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens percentage of net sales of licensed products, subject to standard offsets and reductions as set forth in the HanAll Agreement. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of: (A) the date on which the last valid claim of the licensed patents expires, (B) the date on which the data or market exclusivity expires and (C) 11 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

Except for cost-sharing in connection with the research program, ISG is solely responsible, at its expense, for all other activities related to the research, development and commercialization of licensed products for the HanAll Licensed Territory. ISG may use a third party for manufacturing activities necessary for the research, development and commercialization of licensed products for the HanAll Licensed Territory. In addition, under the HanAll Agreement, ISG has agreed to use commercially reasonable efforts to develop and commercialize licensed products in the HanAll Licensed Territory. Each party to the HanAll Agreement has agreed that neither it nor certain of its affiliates will clinically develop or commercialize certain competitive products in the Licensed Territory.

Under the HanAll Agreement, ISG has the sole right, but not the obligation, to control the prosecution, defense and enforcement of the licensed patents in the HanAll Licensed Territory, and HanAll has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which ISG elects not to exercise such rights.

The HanAll Agreement will expire on a product-by-product basis on the expiration of the last royalty term with respect to a given licensed product, unless earlier terminated. ISG may terminate the HanAll Agreement in its entirety without cause upon 180 days' written notice following 30 days of discussion. Either party may terminate the HanAll Agreement upon 60 days' written notice for uncured material breach (or 30 days in the case of non-payment), or immediately upon written notice if the other party files a voluntary petition, is subject to a substantiated involuntary petition or for certain other solvency events. HanAll may terminate the HanAll Agreement if ISG or its affiliates challenge the validity or enforceability of any of the licensed patents. ISG has commenced discussions with HanAll regarding the future disposition of batoclimab, including the potential return to HanAll of certain rights for batoclimab. In April 2026, ISG notified HanAll of its decision to indefinitely delay further development of batoclimab and focus its resources fully on IMVT-1402. Under the HanAll Agreement, ISG retains final decision-making authority over development and regulatory matters for licensed products in the HanAll Licensed Territory, and ISG believes it has satisfied its obligations under the HanAll Agreement, including with respect to batoclimab. HanAll may disagree with this interpretation of the agreement or ISG's actions thereunder, and ISG may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation.

Pulmovant

License Agreement with Bayer

In July 2023, our subsidiary Pulmovant, Inc. ("Pulmovant") entered into a license agreement (the "Bayer-Pulmovant License Agreement") with Bayer Aktiengesellschaft ("Bayer"). Pursuant to the Bayer-Pulmovant License Agreement, Bayer granted Pulmovant an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and know-how to use, develop, commercialize and manufacture mosliciguat compounds and products containing or comprising such compounds for the prevention, treatment, mitigation, cure and/or diagnosis of any disease in humans or animals.

Pulmovant made an initial payment to Bayer of approximately $14 million and is obligated to pay up to an aggregate of $280 million upon the achievement of certain development, regulatory and net sales milestone events, as well as tiered, high-single-digit royalties on annual net sales of licensed products on a product-by-product and country-by-country basis, subject to certain reductions. Such royalty obligation ends upon the expiration of a customary royalty term, which is the later of (a) the expiration of the last to expire certain specified valid claim of a licensed patent right in such country, (b) the expiration of regulatory exclusivity for such licensed product in such country and (c) a certain amount of years following the first commercial sale of such licensed product in such country.

The Bayer-Pulmovant License Agreement will expire upon the last-to-expire royalty term unless terminated earlier. Either party may terminate for the other party's uncured material breach or insolvency. Bayer has the right to terminate for certain specified patent challenges, and Pulmovant has the right to terminate for convenience.

Genevant

Cross-License Agreement with Arbutus Biopharma Corporation

In April 2018, our subsidiary, Genevant Sciences Ltd. ("GSL"), entered into a cross-license agreement with our affiliate, Arbutus Biopharma Corporation ("Arbutus") (as amended, the "Cross-License Agreement"), which was subsequently assigned to GSL's subsidiary Genevant Sciences GmbH ("Genevant"). Pursuant to the Cross-License Agreement, Arbutus granted Genevant an exclusive, sublicensable, worldwide, transferable, irrevocable and perpetual license under certain patents and know-how relating to Arbutus's lipid nanoparticle and GalNAc technologies for all applications other than hepatitis B virus, and certain other excluded fields. The license is subject to certain rights which had previously been licensed by Arbutus to third parties.

Genevant is obligated to pay Arbutus tiered low single-digit percentage royalties on sales of products covered by the licensed patents. If Genevant sublicenses intellectual property licensed from Arbutus or collaborates with any third-party to develop, manufacture or commercialize any products covered by the intellectual property licensed by Arbutus, it will be required to pay Arbutus the lesser of (i) a percentage (20% in the case of a mere sublicense (i.e., a naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant) of the Royalty-Related Receipts (as defined in the Cross-License Agreement (including the amendments thereto)) received by Genevant from such sublicensees or collaborators and (ii) tiered low single-digit royalties on net sales by sublicensees. Genevant's royalty obligations apply on a product-by-product, country-by-country basis and end on the date on which the last valid claim of the licensed patents in such country that covers such licensed product expires. The patents and pending patent applications, if granted, currently licensed under the Cross-License Agreement began to expire as early as 2023, and end as late as 2041, without giving effect to any potential patent term extensions or patent term adjustments. The Cross-License Agreement includes customary termination rights and, unless earlier terminated, will continue until the expiration of Genevant's royalty obligations.

In the event there are proceeds from an action for infringement by any third parties of Arbutus's intellectual property licensed to Genevant, including the settlement to resolve all patent infringement litigation between Genevant, Arbutus and Moderna pending in the U.S. and internationally entered into in March 2026, Arbutus is entitled to, after deduction of litigation costs, 20% of such proceeds or, if less, tiered low single-digit royalties on net sales of the infringing product (inclusive of the proceeds from litigation or settlement, which would be treated as net sales). For information on the settlement and potential payments related thereto, please refer to Note 5, "Recent Transactions and Developments" of our audited financial statements.

Sales and Marketing

We do not currently have any products that have been approved for commercial sale in the U.S. or any other jurisdiction, and therefore do not have an active sales and marketing capability. Following applicable regulatory approvals for our product candidates, we anticipate sales and marketing activities will be undertaken largely at the Vants, similar to how we structure clinical development activities.

Ahead of the potential commercial launch of brepocitinib for the treatment of DM by Priovant, following applicable regulatory approvals, Priovant is working to establish a sales and marketing function. Priovant intends to build a small, targeted specialty sales organization in the U.S., targeting specialist physicians that treat high numbers of patients with DM and other autoimmune conditions. We believe these physicians treat a majority of patients with DM and the other autoimmune indications for which we intend to seek regulatory approval for brepocitinib and most often serve as the diagnosing and treating physicians for DM and other such indications.

In connection with these commercialization preparations, Priovant is also building dedicated functions across several key commercial capabilities, including a market access function focused on securing formulary coverage and reimbursement from commercial payors, pharmacy benefit managers, Medicare and Medicaid and other government payors; patient support services, including HUB services and patient assistance programs, to facilitate patient access to brepocitinib, following applicable regulatory approvals. We believe the concentrated prescriber base for indications like DM and the other indications for which brepocitinib is currently under development is well-suited to a focused specialty sales model.

We may also opportunistically seek strategic collaborations to maximize the commercial opportunities for brepocitinib and our other product candidates inside and outside the U.S., following applicable regulatory approvals.

As we approach commercialization for our other product candidates, including IMVT-1402 at Immunovant and mosliciguat at Pulmovant, we anticipate they will similarly work to build out sales and marketing functions appropriate to their product candidates, the indications for which they are being developed and prescriber and payor paradigm applicable to those diseases. At the same time, we anticipate certain efficiencies and benefits from shared learnings, experiences and expertise at Roivant and across the Vants as we begin to commercialize multiple product candidates at the Vants.

Manufacturing

We do not currently own or operate facilities for the manufacturing, testing, storage and distribution of clinical or commercial quantities of our product candidates, which include drug substance, drug product and drug-device combination products that we are developing. We currently rely and intend to continue to rely on contract manufacturing organizations ("CMOs") for drug substance, drug product and delivery devices, as well as labeling, packaging and distribution, and we do not have plans to develop our own manufacturing operations in the foreseeable future.

Currently, we contract with well-established third-party manufacturers for the manufacture of our drug substance and our drug product. With respect to brepocitinib, IMVT-1402 and mosliciguat we have either established arrangements or are in the process of establishing arrangements with CMOs to supply drug substance or drug product to support our current and planned clinical trial programs, as well as anticipated commercial supply to support the potential launch of these product candidates following applicable regulatory approvals.

As our clinical needs and commercial plans continue to evolve, we may engage additional third-party manufacturers to support clinical trials for our product candidates as well as commercialization of our product candidates, if approved. In addition, we have personnel with substantial technical and product development experience who actively manage the CMOs producing our product candidates and plan to use such personnel to manage CMOs for any other product candidates or products that we may develop in the future.

Our outsourced approach to manufacturing relies on CMOs to first develop cell lines and manufacturing processes that are compliant with current good manufacturing practice ("cGMP") then produce material for nonclinical studies and clinical trials. Our agreements with CMOs may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream and downstream processes, develop drug product process, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for nonclinical testing, produce cGMP-compliant drug substance or produce cGMP-compliant drug product. We conduct

audits of CMOs prior to initiation of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and cGMP regulations.

In particular, as we approach potential near-term commercialization of brepocitinib, we are working with our CMOs to scale manufacturing processes from clinical to commercial quantities, including conducting or planning process validation activities required for commercial approval. We may also in the future establish relationships with secondary or backup CMOs for drug substance and drug product manufacturing for our most advanced product candidates in order to mitigate supply chain risk and support continuity of commercial supply. We intend to maintain sufficient inventory of drug substance and drug product to support anticipated commercial demand following any regulatory approval, and we believe our existing and planned CMO arrangements will be sufficient to meet our anticipated near-term commercial supply requirements.

Competition

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. We expect to face intense competition from other biopharmaceutical companies who are developing agents for the treatment of autoimmune diseases and pulmonary hypertension.

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), FcRn blockers, potential competitors to brepocitinib and IMVT-1402;
- IMAAVY (nipocalimab-aahu) and RYSTIGGO (rozanolixizumab-noli), FcRn blockers, potential competitors to IMVT-1402;
- Dazukibart, an interferon beta (IFN-beta) inhibitor, a potential competitor to brepocitinib; and
- Tyvaso (treprostinil) and Yutrepia (treprostinil), prostacyclin mimetics, potential competitors to mosliciguat.

Our product candidates, if approved, may also face competition from agents with different mechanisms of action.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. For example, in October 2023, Amgen completed its previously announced acquisition of Horizon Therapeutics for approximately $27.8 billion, expanding its rare disease pipeline, and in October 2025, Merck completed its acquisition of Verona Pharma for approximately $10 billion, strengthening its cardio-pulmonary portfolio. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Accordingly, competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our targeted indications by a competitor could render our product candidates non-competitive

or obsolete, or reduce the demand for its product candidate before it can recover its development and commercialization expenses.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technologies and know-how; to operate without infringing, misappropriating or otherwise violating the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We may also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the fields of genetic therapy, cell therapy, biologics or pharmaceutical products generally has emerged in the U.S., Europe or the rest of the world. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in such territories or jurisdictions may diminish our ability to protect our product candidates and enforce our intellectual property rights, and more generally could affect the value of our intellectual property, including our product candidates. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions and improvements. We cannot be sure that any patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates and technology. Moreover, our issued patents and those that may be issued in the future may not guarantee us the right to practice our technology in relation to the commercialization of our product candidates, if approved, or technology. The area of patents and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, which may prevent us from commercializing our product candidates and practicing our proprietary technology.

Our issued patents and those that may be issued in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related products or technologies or limit the length of the term of patent protection that we may have for our product candidates and technologies. In addition, the rights granted under any issued patents may not provide us with complete protection or competitive advantages against competitors or other third parties with similar technology. Furthermore, our competitors may independently develop similar technologies that achieve similar outcomes but with different approaches. For these reasons, we may have competition for our product candidates. Moreover, the time required for development, testing and regulatory review of our product candidates may shorten the length of effective patent protection following commercialization. For this and other risks related to our proprietary technology, inventions, improvements, platforms and product candidates, please see the section entitled “Risk Factors—Risks Related to Roivant’s Business and Industry—Risks Related to Our Intellectual Property.”

Patents and Patent Applications

Priovant

As of March 31, 2026, Priovant Therapeutics, Inc. has (1) exclusively licensed rights to six patent families for brepocitinib containing at least 202 issued patents and 53 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering, among other things, a composition of matter, a crystalline form, a topical formulation, a process for making brepocitinib, a treatment of hidradenitis, a dosage regimen for treatment of hidradenitis and treatment of dermatomyositis with brepocitinib. These patents and pending applications, if issued, are expected to expire as early as 2035, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, and (2) exclusively licensed rights to three patent families for ropsacitinib containing at least 154 issued patents and 27 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering a composition of matter, a treatment of hidradenitis and a crystalline form. These patents and pending applications, if issued, are expected to expire as early as 2037, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Anti-FcRn Franchise

Following ISG's assumption of all rights, title, interest and obligations under the HanAll Agreement from RSG in December 2018, by virtue of the license of patent rights under the HanAll Agreement, ISG became the exclusive licensee of certain patents, patent applications and know-how directed to batoclimab, IMVT-1402 and certain back-up and next-generation antibodies, and products containing such antibodies, in the HanAll Licensed Territory. In January 2026, Immunovant completed an internal reorganization and transfer of intellectual property rights related to Immunovant's product candidates between two wholly-owned subsidiaries of Immunovant. As of January 14, 2026, IMVT Corporation ("IMVT Corp") assumed control of all intellectual property rights directed to batoclimab, IMVT-1402 and certain back-up and next-generation antibodies, and products containing such antibodies, in the HanAll Licensed Territory.

As of March 31, 2026, the in-licensed patent portfolio includes a patent family covering batoclimab with pending patent applications and/or issued patent(s) in the U.S., Argentina, Brazil, Canada, European Patent Office, Egypt, Israel, Mexico and Saudi Arabia. This in-licensed patent family was filed in 2015 and discloses anti-FcRn antibodies, including batoclimab, pharmaceutical compositions thereof, methods of treating autoimmune disease using the same, polynucleotides encoding such antibodies, expression vectors including such polynucleotides, host cells transfected with such recombinant expression vectors, methods of manufacturing such antibodies and methods of detecting FcRn in vivo or in vitro using such antibodies. Notably, in this in-licensed patent family, a U.S. patent was issued on July 2, 2019, with claims directed to batoclimab as defined by its CDRs and epitope or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof. Furthermore, another U.S. patent was issued in this in-licensed patent family on January 28, 2020, with claims directed to batoclimab as defined by its CDRs or antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of producing such antibody or antigen-binding fragment. A further patent was issued in the U.S. on March 31, 2023 with claims to two an isolated anti-FcRn antibodies other than batoclimab or an antigen-binding fragment thereof, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment thereof, polynucleotides and expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. A European patent in this family was issued on May 10, 2023 with claims directed to batoclimab as defined by its heavy and light chain variable sequences. There are also issued patents in this family in Brazil, Canada, Israel, Mexico and Saudi Arabia. In this family, applications are pending in Argentina, Mexico, the U.S. and in Europe. The patents of this patent family may expire in 2035, 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 addition, the in-licensed patent portfolio includes another patent family that discloses a pharmaceutical formulation for an anti-FcRn antibody. This patent family includes pending applications in the U.S., and in Europe, Israel, Canada, Mexico and Argentina, and any patent issued in this patent family may expire in 2041, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Additionally, as of March 31, 2026, independent of the licensed patent portfolio, IMVT Corp owns a patent family directed to methods of treating thyroid eye disease (a.k.a. Graves' ophthalmopathy) using anti-FcRn antibodies that include pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Europe, Israel and Mexico. Any patent issued from this patent family may expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Further, IMVT Corp owns a patent family directed to and methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies that include pending patent applications in the U.S. and in European Patent Office. Any patent issued from this patent family may expire in 2040, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp jointly owns rights with HanAll to a patent family covering IMVT-1402 and its uses to treat autoimmune disease, which includes patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Colombia, Egypt, European Patent Office, Israel, Mexico, Panama, Peru and Saudi Arabia. Notably, in this patent family, a U.S. patent was issued on March 12, 2024, with claims directed to IMVT-1402 as defined by its CDRs, a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof, and methods of treating an autoimmune disease using such antibody or antigen-binding fragment thereof, polynucleotides and

expression vectors encoding the same, host cells transfected with such expression vectors and methods of preparing such antibody or antigen-binding fragment. The patents of this patent family may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns patent families directed to methods of treating Graves' disease and methods of treating CIDP using anti-FcRn antibodies including IMVT-1402 and batoclimab, which include pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Chile, Colombia, Egypt, Europe, Israel, Mexico, and Saudi Arabia. Any patent issued from these patent families may expire in 2043, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a patent family directed to high concentration protein formulations with polysorbate excipients and methods of making the same, which includes pending patent applications in the U.S. as well as foreign counterparts in certain jurisdictions including Brazil, Canada, Europe, and Mexico. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a Patent Cooperation Treaty ("PCT") application directed to methods of improving anti-FcRn therapies, which describes specific dosing regimens for IMVT-1402. Any patent issued from this patent family may expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity or other governmental fees. For information regarding ISG's license agreement with HanAll, please see "—Vant License Agreements & Other Vant Agreements."

IMVT Corp also owns a PCT application and a corresponding Argentine application directed to formulations for anti-FcRn antibodies. Any patent issued from this patent family may expire in 2045, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

IMVT Corp also owns a PCT application and a corresponding Argentine application directed to methods of treating skin diseases using anti-FcRn antibodies including IMVT-1402 and batoclimab. Any patent issued from this patent family may expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

IMVT Corp also owns a U.S. provisional application directed to methods of inducing remission in GD patients using anti-FcRn antibodies including IMVT-1402 and batoclimab. Any patent issued from this patent family may expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

IMVT Corp owns a registered trademark for IMMUNOVANT and the combination of its logo Y-shaped antibody and IMMUNOVANT in the United States and many other jurisdictions throughout the world for goods and services. As of March 31, 2026, this trademark portfolio includes pending trademark applications and registered trademarks in the U.S. and foreign jurisdictions. Under the HanAll Agreement, ISG has the right to market IMVT-1402 and batoclimab in the HanAll Licensed Territory under the trademarks of ISG's choice, subject to regulatory approval. However, upon termination of the HanAll Agreement, ISG must assign to HanAll all rights, title and interest in and to any and all trademarks ISG uses in the development, manufacture or commercialization of the licensed products.

Pulmovant

As of March 31, 2026, Pulmovant, Inc. has exclusively licensed rights to five patent families for mosliciguat containing at least 86 issued patents and 75 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering the composition of matter, a crystalline form, a formulation for inhalation, a process for making mosliciguat, a treatment of cardiopulmonary disorders, including PH Group 3, and a dosage regimen for treatment of cardiopulmonary disorders, including PH Group 3. These patents and pending applications, if issued, are expected to expire between 2033 and 2042, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Genevant

As of April 6, 2026, Genevant Sciences GmbH ("GSG") owns or co-own 29 patent families containing 45 issued patents and 118 pending patent applications in the U.S., European Union and numerous other jurisdictions, including claims relating to lipid nanoparticle delivery technology, polymers and nucleic acid delivery constructs. These patents and pending applications, if issued, are expected to expire between 2029 and 2045, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of April 6, 2026, GSG has licensed 28 patent families containing 485 issued patents and 110 pending patent applications in the U.S., European Union and numerous other jurisdictions, including claims relating to delivery systems. These patents and pending applications, if issued, are expected to expire between June 2025 and 2041, in each case without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Trade Secrets

In addition to our reliance on patent protection for our inventions, product candidates and research programs, we also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. As a result, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Roivant's Business and Industry—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, as well as diagnostics, and any future product candidates. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized or cleared by the applicable regulatory authority.

U.S. Government Regulation of Drug and Biological Products

In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations and biologics under the FDCA and the Public Health Service Act (the "PHSA"), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following regulatory approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, debarment from producing or marketing drug products or biologics, disqualification from conducting research and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our product candidates and our reputation.

Our product candidates must be approved by the FDA through either an NDA or a BLA process before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB, or independent ethics committee for each clinical trial site before each human trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and requirements, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA inspection of the clinical trial sites that generated the data in support of the NDA or BLA and us as the sponsor;
- payment of user fees for FDA review of the NDA or BLA (unless a fee waiver applies);
- agreement with the FDA on the final labeling for the product and the design and implementation of any required REMS; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the U.S.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. In the U.S., the conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for nonclinical (e.g., safety/toxicology) studies.

In the U.S., an IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue, and additional preclinical testing may commence, after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Additionally, the review of information in an IND submission may prompt the FDA to, among other things, scrutinize existing INDs or marketed products and could generate requests for information or clinical holds on other product candidates or programs.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. In the U.S., each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in such use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

In March 2022, the FDA finalized a guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," the draft of which was released in August 2018. This final guidance outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development, i.e., the first-in-human clinical trial, to compress early phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA or post-approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected AEs, findings from

other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at an institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the U.S.

Under the Prescription Drug User Fee Act (the "PDUFA"), as amended, each NDA or BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the application also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification. During the COVID-19 pandemic, because of travel and other restrictions, the FDA significantly curtailed its inspection program. The reduction in pre-approval inspections resulted in delays to some product approvals. Even with the mostly complete resumption of the FDA's normal inspection program and continued use of alternative inspection tools, there may be delays to product approvals in the future based on a resurgence of, or new problems with respect to the FDA's ability to conduct inspections and then, even after a complete resumption of the FDA's normal inspection program, a possible backlog in applications under review by the agency.

The FDA has developed the Oncology Center of Excellence RTOR pilot program to facilitate a more efficient review process for certain oncology product candidates. Although this program allows the FDA to begin reviewing clinical data prior to submission of a complete NDA or BLA, the program is not intended to change the PDUFA review timelines.

Before approving an NDA or BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require the applicant to obtain additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than

200,000 individuals in the U.S. or affects more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making in the U.S. a drug for such disease or condition will be received from sales in the U.S. of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher (a "PRV"). A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress reauthorized the rare pediatric disease PRV program through September 30, 2029.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the development, FDA review and approval of new drugs and biologics that meet certain criteria. For example, the FDA has a fast-track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

A product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review and accelerated approval. Priority review means that, for an NDA for a new molecular entity or original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A product is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review. If criteria are not met for priority review, the NDA for a new molecular entity or original BLA is subject to the standard FDA review period of ten months after the FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition, generally provides a meaningful advantage over other available therapies, and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. The FDA may require such trials to be underway prior to, or within a specific period after, approval and will specify the conditions for such studies. Further, sponsors must provide reports on post-marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed. The failure to conduct required post-approval clinical trials with due diligence and the failure to submit the required reports are prohibited acts. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial is not conducted or fails to verify the predicted clinical benefit of the product. The FDA can withdraw accelerated approvals on an expedited basis provided certain procedures are followed.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in

clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough Therapy Designation comes with all of the benefits of fast-track designation, which means that the sponsor may file sections of the NDA or BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

The FDA has also announced the availability of the RTOR pilot program for oncology product candidates that are likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted Breakthrough Therapy Designation for the same or other indications and candidates meeting other criteria for other expedited programs, such as fast track and priority review. Submissions for RTOR consideration should also have straightforward study designs and endpoints that can be easily interpreted (such as overall survival or progression free survival). Acceptance into the RTOR pilot does not guarantee or influence approvability of the application, which is subject to the usual benefit-risk evaluation by FDA reviewers, but the program allows the FDA to review data earlier, before an applicant formally submits a complete application. The RTOR pilot program does not affect FDA's PDUFA timelines.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval and Breakthrough Therapy Designation do not change the standards for approval.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act (the "PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and, for drug products, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-Marketing Requirements

Following regulatory approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences and certain problems in the manufacturing process, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-

label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and any promotion that is false or misleading, and a company that is found to have improperly promoted off-label uses or in a false or misleading manner may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals, including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals;
- drug or biologic seizure or detention, or refusal to permit the import or export of drugs;
- injunctions or the imposition of civil or criminal penalties; or
- debarment from producing or marketing drug products or biologics.

Regulation of Companion Diagnostics

Success of certain product candidates may depend, in part, on the development and commercialization of a companion diagnostic. A companion diagnostic is a medical device, typically an *in vitro* device, which provides

information that is essential for the safe and effective use of a corresponding drug or biological product. Companion diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are generally regulated as medical devices by the FDA. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance through the premarket notification process ("510(k) clearance") or premarket approval from the FDA prior to commercialization.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or other predicate devices, for which the FDA has not yet called for the submission of a premarket approval ("PMA"). In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will typically conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality Management System Regulation (the "QMSR"), which requires manufacturers to follow design, testing, control, corrective and preventative action, documentation and other quality assurance procedures. The FDA's review of an initial PMA application is generally required by statute to take six months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of FDA's QMSR, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug and biologic makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA is able to conduct an inspection of the product(s) and the company's facilities for compliance with its authorities.

The FDA has taken the position that developers of companion diagnostic tests associated with novel therapeutic products should seek clearance or approval at the same time that the therapeutic developer seeks approval. The FDA has recognized that contemporaneous clearance or approval of a companion diagnostic with a therapeutic is not always possible, though the FDA has indicated that coordination of contemporaneous clearances/approvals is a policy goal. In October 2018, the FDA issued a safety alert warning against the use of unapproved or uncleared genetic tests to predict patient response to specific medications. While the FDA has historically exercised enforcement discretion against laboratory developed tests—tests which are developed and performed in a single Clinical Laboratory Improvement Amendments certified laboratory—the 2018 alert and a subsequent 2019 Warning Letter against Inova Genomics Laboratory suggested that FDA may prioritize for enforcement certain uncleared or unapproved tests marketed as companion diagnostic tests. Subsequently, the FDA has attempted to encourage collaboration between *in vitro* diagnostic test developers and therapeutic developers and to clarify FDA expectations as to companion diagnostic labeling, particularly through guidance in the oncology area. In September 2023, the FDA announced a proposed rule, which was published in October 2023, to revise the regulatory definition of an in vitro diagnostic product to explicitly capture laboratory developed tests and make clear that such tests are medical devices subject to FDA regulation. The proposed rule also described a proposed policy under which the FDA will gradually end its general enforcement discretion policy for

laboratory developed tests in phases over a four-year period. The FDA subsequently issued the final rule in May 2024, including its policy for phasing out its general enforcement discretion policy for laboratory developed tests. In March 2025, the Eastern District of Texas vacated the final rule in consolidated cases challenging the rule. The FDA declined to appeal the ruling and rescinded the final rule in September 2025.

Biosimilars and Exclusivity

Certain of our product candidates, including batoclimab, are regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (the "BPCI Act"), as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act" or "ACA"). This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, make this abbreviated pathway more complicated than that for generic, small molecule drugs.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, including the Centers for Medicare and Medicaid Services (the "CMS"), the Office of Inspector General and Office for Civil Rights, other divisions of the Department of HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians and third-party payors will play a primary role in making clinically-appropriate decisions enabling patient access to any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and physicians and any future arrangements with third-party payors, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the U.S., these laws include: the federal Anti-Kickback Statute, the False Claims Act and the Health Insurance Portability and Accountability Act ("HIPAA").

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that 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 federal civil False Claims Act.

Drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim; the potential for exclusion from participation in federal healthcare programs, which would preclude reimbursement of our products under the Medicare and Medicaid programs; and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing certain billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to federal, state and commercial reimbursement for our product candidates, following regulatory approval, and the sale and marketing of our product candidates, are subject to scrutiny under this law.

HIPAA created federal criminal statutes that prohibit among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like 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 in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

We are subject to data privacy and security regulations administered and enforced by the federal government as well as statutes and regulations adopted in the states in which we conduct our business. At the federal level, the FDA regulations for the protection of human research subjects require that we protect the privacy of personal information and obtain appropriate informed consent in connection with research using identifiable subject information or identifiable biological samples. In addition, the data privacy and security regulations implementing HIPAA impose strict limitations on the use and disclosure of individually identifiable health information, including for research purposes. Civil and criminal penalties may be imposed on entities subject to HIPAA, both by the HHS Office for Civil Rights and by state attorneys general, who have the authority to file civil actions for damages or injunctions in federal courts to enforce the HIPAA privacy, security and security breach notification regulations and to seek attorney's fees and costs associated with pursuing such actions. In addition, the Federal Trade Commission has broad authority to investigate and initiate enforcement actions regarding any activity affecting the privacy or security of personal information that it deems deceptive or unfair. At the state level, a rapidly growing body of privacy and data protection laws impose requirements and restrictions, some of which are more stringent than federal law and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act"), within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions)

report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians, certain other healthcare professionals and teaching hospitals and to report annually certain ownership and investment interests held by physicians, certain other healthcare professionals and their immediate family members. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not preempted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the U.S. and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare.

For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013, following passage of the Bipartisan Budget Act of 2013, and will remain in effect through the first six months of 2032 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act were suspended from May 1, 2020

through March 31, 2022 due to the COVID-19 pandemic. There was a 1% reduction through the end of June 2022, after which the cuts returned to 2%. Absent Congressional action, there also was a possibility that an up to 4% Medicare sequester could be triggered in January 2025, pursuant to the Statutory Pay-As-You-Go Act of 2010 ("PAYGO"). Under PAYGO, if the five- or ten-year PAYGO scorecard shows a net cost at the end of a Congressional session, then the Office of Management and Budget is required to issue a sequestration order. However, in December 2024, Congress enacted the American Relief Act, which set the balances on both PAYGO scorecards to zero for all years, effectively waiving any potential sequestration under the Statutory PAYGO Act of 2010. Finally, the American Rescue Plan Act of 2021 eliminated the Medicaid unit rebate AMP cap effective as of January 1, 2024, and the removal of this rebate cap could significantly impact our Medicaid rebate liability for any future products.

There has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. In August 2022, Congress enacted the Inflation Reduction Act ("IRA"), a law that included sweeping changes to the payment for drugs under the Medicare program. Among other provisions, the IRA contains (i) a drug price negotiation program for certain high-spend Medicare drugs that have been on the market for a certain length of time and lack generic or biosimilar competition, under which Medicare prices for such drugs are capped by a "maximum fair price"; (ii) new manufacturer rebate obligations on certain drugs paid under Medicare Part B or D whose prices increase faster than inflation relative to a benchmark period; and (iii) a redesign of the Part D benefit, including capping patients' annual out-of-pocket costs on Part D drugs, lowering the beneficiary out-of-pocket threshold, streamlining the Part D benefit to eliminate the "coverage gap" phase, and replacing the manufacturer coverage gap discount program with a new manufacturer discount program – the Medicare Part D Manufacturer Discount Program – that provides discounts throughout the post-deductible benefit phases. CMS has established "maximum fair prices" for selected drugs for coverage year 2026 and coverage year 2027. Additionally, 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. The impact of the IRA on research and development, the pharmaceutical supply chain and other aspects of our business and industry remains uncertain. Over time, provisions of the IRA could increase our government discount and rebate liabilities, reduce the revenues we may eventually be able to collect from sales of our products as well as present potential challenges for payor negotiations and formulary access.

In October 2022, former President Biden issued executive order 14087 calling on the Secretary to consider whether to select for testing by the CMS innovation center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. In response, the CMS innovation center released a report in February 2023, identifying three selected models: Medicare High-Value Drug Model, the Cell & Gene Therapy Access Model, and the Accelerating Clinical Evidence Model. However, within his initial days in office, President Trump issued an executive order rescinding former President Biden's executive order 14087, thereby cancelling the Medicare High-Value Drug Model and the Accelerating Clinical Evidence Model. HHS has indicated, however, that the Cell & Gene Therapy Access Model will continue as planned.

The Trump Administration has pursued new or different drug pricing, trade, 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, and as discussed further below, the Trump Administration is seeking to institute most-favored-nation ("MFN") pricing through legislative changes. Legislative proposals have been introduced in Congress that would mandate MFN pricing for particular healthcare programs, if enacted. In addition, President Trump took executive action to end diversity, equity, and inclusion initiatives among public-sector contractors and grantees. Additionally, in February 2025, the Department of Health and Human Services ("HHS") announced that it is rescinding agency policy regarding public participation in certain kinds of HHS rulemaking, known as the Richardson Waiver. Under the Richardson Waiver, HHS waived a statutory exemption that allowed the agency to enact regulation on matters relating to "agency management or personnel or to public property, loans, grants, benefits or contracts" without engaging in notice-and-comment rulemaking, except as otherwise required by law. Now that the Richardson Waiver has been revoked, HHS may opt not to seek public comment on regulations related to these types of matters, which may prevent us from meaningful engagement in the rulemaking process. However, the extent to which HHS will use its discretion not to provide notice-and-comment procedures or the specific topics it views as subject to the Richardson Waiver remain unknown at this time. Moreover, the Trump Administration announced plans to restructure HHS, including substantial reductions in work force. It is not clear how this restructuring will impact our business. Finally, the Trump Administration has announced broad tariffs on foreign imports, which in many cases has caused other nations to levy retaliatory tariffs on goods manufactured in the United States. On April 2, 2026, a Presidential Proclamation imposed tariffs on certain pharmaceutical products, active pharmaceutical ingredients, and key starting materials. The tariffs, which range from 10 percent to 100 percent

depending on various factors, including type of drug and country of origin, are also subject to a number of exemptions and exclusions. Additional guidance from implementing agencies is necessary to provide details on the application of the tariffs, which generally will not go into effect until September 2026. These tariffs could impact our costs for raw materials and manufacturing as well as the market for our future products. Some of the Trump Administration's policy initiatives, including the tariffs on pharmaceuticals, may be subject to litigation, increasing the uncertainty of their effects on our business.

It is possible that Congress or the Administration may take further actions to control drug prices. Further federal, state and foreign legislative and regulatory developments are likely, and we expect these already enacted and ongoing initiatives to increase pressure on drug pricing. Reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. In particular, the obligation to provide notices of price increases to purchasers under laws such as California's SB-17 may influence customer ordering patterns for our product candidates, following regulatory approval, which in turn may increase the volatility of our revenues as a reflection of changes in inventory volumes. In addition, some state legislatures have established Prescription Drug Affordability Boards ("PDABs"), which under certain circumstances may conduct affordability reviews and establish upper payment limits ("UPLSs") for drugs purchased in the state. For example, on August 4, 2023, the Colorado PDAB commenced an affordability review of five prescription drugs, including three products that are indicated to treat plaque psoriasis (ENBREL®, COSENTYX®, STELARA®). Amgen subsequently brought suit challenging the legality of the Colorado PDAB's efforts to set a UPL for ENBREL, but that suit was dismissed without prejudice in March 2025 for lack of standing, in part because the Colorado PDAB has not yet issued UPLs impacting Amgen's products. Amgen brought a second suit challenging the legality of the Colorado PDAB's efforts to set a UPL for ENBREL in October 2025. This suit is pending. We cannot predict the outcome of such state PDAB affordability reviews or payment limitations or their impact on our future products. We may continue to see additional state action related to prescription drug pricing.

Packaging and Distribution in the United States

If our product candidates are made available to authorized users of the Federal Supply Schedule of the General Services Administration once approved, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale, diversion or misuse of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our 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.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future products, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

European Union and United Kingdom Drug Development

On June 23, 2016, the electorate in the U.K. voted in favor of leaving the European Union (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw

pursuant to Article 50 of the Lisbon Treaty. The U.K. formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which E.U. pharmaceutical law remained applicable in the U.K. However, this ended on December 31, 2020. On December 30, 2020, the U.K. 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, on March 24, 2023, an agreement was reached by the U.K. and E.U. (the "Windsor Framework"), relating to post-Brexit trade issues in Northern Ireland, which has applied from January 1, 2025. The Windsor Framework seeks to simplify the supply of medicines between Great Britain and Northern Ireland and means the E.U. legislation does not apply in all cases in Northern Ireland. Since the regulatory framework in the U.K. 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 has begun to impact the regulatory regime which applies to products and the approval of product candidates in the U.K., as U.K. legislation may now diverge from E.U. legislation, which it has done in various areas, including medical device regulation and clinical trials. In addition, updates to E.U. legislation made after December 31, 2020 do not apply in the U.K. The MHRA has published detailed guidance for industry and organizations on the positions in the U.K., and continues to update them as the U.K.'s regulatory position on medicinal products and medical devices evolves. The legislation on medical devices is currently being amended on a rolling basis with additional changes expected in 2026, and a revised regulatory regime on clinical trials will come into effect in the U.K. on April 28, 2026.

In the EEA, which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, and in the U.K., our future products also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the relevant competent authority has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in the EEA and U.K. are subject to significant regulatory controls.

The E.U. clinical trials legislation underwent a transition process due to the application of the new Clinical Trials Regulation (E.U.) No 536/2014 (the "Regulation"), which is mainly aimed at harmonizing and streamlining clinical trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the E.U. adopted the Regulation, which started to apply on January 31, 2022 and replaced the previous Clinical Trials Directive 2001/20/EC (the "Directive"). Specifically, the new Regulation, which is directly applicable in all Member States without the need for E.U. Member States to transpose it into national law, aims at simplifying and streamlining the approval of clinical trials in the E.U. For instance, the new Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It also provides for increased transparency and proactive publication of clinical trial documents and results, subject to certain exceptions and derogations.

Following Brexit, this Regulation is not applicable in the U.K., and the national legislation put in place to implement the Directive, and amended to reflect the U.K.'s withdrawal from the E.U., continues to apply to trials conducted in the U.K. However, amendments to the 2004 Regulations, effected through the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024, will come into force on April 28, 2026. These reforms are intended to streamline clinical trial approvals, enable innovation, enhance clinical trial transparency, enable greater risk proportionality, and promote patient and public involvement.

European Union and United Kingdom Drug Marketing

Much like the federal Anti-Kickback Statue prohibition in the U.S., the provision of benefits or advantages to physicians and healthcare organizations to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, administration or use of medicinal products is also prohibited in the EEA and U.K. under E.U. Directive 2001/83/EC, which is the Directive governing medicinal products for human use, as implemented in the relevant Member State and implemented in the U.K. via the Human Medicines Regulations 2012, the national anti-bribery laws of the European Union Member States, and the Bribery Act 2010 and Economic Crime and Corporate Transparency Act 2023 in the U.K., as well as the industry Codes of Practice that are based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice, including the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry in the U.K, collectively prohibit the provision of benefits or advantages to induce or reward improper performance. Infringement of these laws could result in substantial fines and imprisonment. E.U. Directive 2001/83/EC further provides that, where medicinal products are being promoted to persons qualified to

prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the national laws of the E.U. Member States, as well as in the U.K. Human Medicines Regulations 2012 and so remains applicable in the U.K. despite its departure from the E.U. Promotion of prescription-only medicinal products to an audience other than healthcare professionals is prohibited in the EEA and the U.K. As of September 1, 2025, in the U.K., the Economic Crime and Corporate Transparency Act 2023 introduced a provision relating to failure to prevent fraud, whereby a company will be guilty of an offence if it fails to prevent fraud by an associate subject to the defence that reasonable prevention procedures were in place at the time the fraud was committed. This provision would capture acts of a healthcare professional providing a service for a company.

Depending on the applicable national rules in the E.U. Member States and the U.K., payments and other transfers of value made to physicians, physician associations, medical students, healthcare organizations, patient organizations and other stakeholders in the E.U. Member States, the U.K. and Member States of the EEA must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and the regulatory authorities of the individual country. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the relevant country. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Union and United Kingdom Drug Review and Approval

In the EEA, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). There are two main types of marketing authorizations for innovative medicinal products, which, however, are based on largely identical regulatory rules, requirements and timelines, including the requirements concerning the presentation and content of the application for marketing authorization.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (the "CHMP"), of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. If a product is to be authorized in more than one Member State, the assessment procedure is coordinated between the relevant E.U. Member States. Where a product has already been authorized for marketing in a Member State of the EEA, the national MA can be recognized in another Member State through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (the "RMS"). The competent authority of the RMS coordinates the preparation of a draft assessment report, a draft summary of the product characteristics (the "SmPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States) for their final approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging circulated by the RMS, the coordinated procedures is closed, and the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above-described procedures, during the assessment of the documents submitted in the marketing authorization application ("MAA") and before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria

concerning its quality, safety and efficacy. The centralised MAs are granted by the European Commission, where the national MAs are granted by the competent authorities of the Member States of the EEA.

Now that the U.K. has left the European Union, and following the changes introduced by the Windsor Framework, the countries of the U.K. are no longer covered by centralized MAs. On January 1, 2024, the International Recognition Procedure ("IRP") was introduced, whereby the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the U.K. medicines regulator, may rely on a decision taken by other international regulators, including the European Commission and the U.S. FDA, in order to more quickly grant a new MA valid in Great Britain or the U.K. A separate application will, however, still be required and the MHRA has the right to undertake its own assessment of the dossier. There are two such routes, allowing recognition in a 60-day or 110-day timelines. The IRP is in addition to the MHRA's national procedures, including the shortened 150-day timetable.

European Union and United Kingdom Data Protection and Market Exclusivity

In the EEA and U.K., innovative medicinal products, approved on the basis of a full dossier of preclinical and clinical data as part of the MAA, qualify for eight years of data protection upon notification of marketing authorization and an additional two years of market exclusivity. The data protection, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference innovative product when applying for a generic or biosimilar MA in the EEA/U.K., for a period of eight years from the date of notification of authorization of the reference product. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period of market exclusivity can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if an innovative medicinal product gains the prescribed period of data protection, however, another company may market another version of the product if such company obtained a MA based on a marketing authorization application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials (i.e., without cross-referencing to the data within the reference innovative product).

In March 2026, the E.U. institutions agreed to the text of legislation constituting the reform of the E.U. regulatory framework for medicinal products. The new legislation, set to apply to new marketing authorization applications in late 2028 or early 2029, amends the exclusivity periods such that the new standard period of protection in the E.U. will be nine years, made up of eight years of data protection and one year of market exclusivity. The market exclusivity period can be extended by up to 3 years if certain conditions are fulfilled under the incoming legislation. The U.K. framework reflects the existing E.U. framework set out in the paragraph above, and the E.U. reforms will not apply in the U.K.

European Union and United Kingdom Orphan Designation and Exclusivity

In the EEA, the European Commission, based on the scientific assessment from 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 life-threatening or chronically debilitating conditions and either (i) such condition affects not more than five in 10,000 persons in the EEA, or (ii) it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development. In either case, the applicant must also demonstrate that no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected compared to the product available).

In the EEA, orphan drug designation entitles a party to benefits such as scientific advice (protocol assistance) and financial incentives such as reduction of fees or fee waivers. In addition, if the criteria for orphan designation are found to be maintained at the time of authorization of the product, ten years of market exclusivity is granted following grant of an orphan marketing authorization. During this market exclusivity period, neither the EMA nor the European Commission nor any of the competent authorities in the EEA Members States can accept an application or grant a marketing authorization for a "similar medicinal product" for the same indication. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This orphan exclusivity period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity may also be broken, so a similar product may be authorized for the same indication, in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective

or otherwise clinically superior to the authorized product; (ii) the marketing authorization holder consents to the grant of marketing authorization for the similar product; or (iii) the marketing authorization holder cannot supply enough orphan medicinal product. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process and must be confirmed at the time of grant of the marketing authorization (i.e., reassessment of compliance with the orphan designation criteria).

The new legislation reforming the E.U. regulatory framework for medicinal products mentioned above will also significantly change the regulatory regime applicable to) the orphan exclusivities. The incoming legislation changes the concept of unmet medical need and considers introducing additional rewards for orphan medical products considered to be breakthrough orphan medicinal products (i.e., orphan medicinal products addressing a disease with no current available medicinal treatment and which bring a clinically relevant reduction in morbidity or mortality).

Following Brexit, a separate process for orphan drug designation applies in 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 Framework on January 1, 2025, marketing authorizations for orphan products cover the whole of the U.K.

European Union and United Kingdom Pediatric Investigation Plan

In the EEA and U.K., MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (a "PIP"), agreed with the EMA's Pediatric Committee (a "PDCO") or MHRA as relevant. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization, a new indication, pharmaceutical form or route of administration is being sought. The PDCO/MHRA can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO/MHRA when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. If a marketing authorization is obtained and trial results are included in the product information, even when negative, and the product is approved in all Member States, non-orphan products are eligible for six months' supplementary protection certificate extension. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

As noted above, the upcoming legislative reforms in the E.U., which are part of the new E.U. Pharmaceutical Strategy may, potentially result in a removal of the two-year extension of the orphan market exclusivity (to be replaced with six months' supplementary protection certificate extension) and imposition of additional requirements for grant of rewards.

European Union and United Kingdom Data Protection Regime

The processing of personal data, including health data, in the EEA is governed by the General Data Protection Regulation (the "GDPR"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the European Union or EEA or the monitoring of the behavior of data subjects in the European Union or EEA. The GDPR enhances data protection obligations for data controllers of personal data, including inter alia stringent requirements relating to lawful and legitimate basis and purposes for the processing of personal data, the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, appointment of a data protection officers, conclusion of data processing agreements, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. In the past, one such data transfer mechanism was the E.U.-U.S. Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union ("CJEU"). In July 2023, the U.S. and E.U. implemented the E.U.-U.S. Data Privacy Framework ("DPF") replacing the invalidated Privacy Shield.

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. The U.K. Extension to the E.U.-U.S. Data Privacy Framework ("Data Bridge") entered into force in October 2023, allowing certifying entities to transfer personal data from the U.K. to the U.S. It is unclear whether any 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 if changes introduced in the U.S. 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.

In July 2020, the CJEU upheld the validity of standard contractual clauses ("SCCs") as a legal mechanism to transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection and in July 2021, the European Commission adopted new SCCs. Even so, 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 U.S. 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 and product development.

The competent authorities and courts in a number of E.U. Member States continue to closely scrutinize and question the GDPR compliance of processing of personal data by U.S.-based entities or entities with links to U.S.-based entities, independently of whether personal data is actually transferred outside the EEA. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. 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.

In addition, further to the U.K.'s exit from the European Union on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain U.K. specific amendments) into U.K. law, referred to as the U.K. GDPR. While the GDPR and the U.K. GDPR remain substantially similar for the time being, the government of the U.K. has adopted reforms to its data privacy and cybersecurity legal framework in its Data Use and Access Act 2025, which became law on June 19, 2025 (phasing in between June 2025 and June 2026) and will introduce significant changes from the GDPR. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. 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. This initial U.K. adequacy decision was extended by the European Commission once in June 2025 for a period of six months and in December 2025 for a new period of six years, expiring on December 27, 2031 with the possibility to be further renewed. The European Commission will review the functioning of the adequacy decision after a period of four years and the adequacy decision may be modified or unilaterally revoked by the European Commission at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

Rest of the World Regulation

For other countries outside of the European Union and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products and operating restrictions.

Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act (the "FCPA"), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Further, other anti-corruption laws, such as the U.K. Bribery Act, are broader and can regulate payments to non-governmental entities.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government programs, such as Medicare and Medicaid, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are covered or paid for by the federal or national government as well as commercial managed care organizations, pharmacy benefit managers and similar healthcare management organizations.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment, and efforts of third-party payors to contain or reduce health care costs may adversely affect our ability to establish or maintain appropriate prices for our product candidates following regulatory approval. Such efforts include the use of accumulator adjustment programs that do not consider amounts paid by pharmaceutical copay assistance programs as counting towards a patient's deductible or other out-of-pocket costs. Under new rules promulgated by CMS that would have taken effect January 1, 2023, such accumulator adjustment (or similar) programs could affect the amount of rebates owed by manufacturers under the Medicaid Drug Rebate Program or affect our ability to offer various forms of patient support, including copay assistance. However, this regulation was struck down in Federal court in May 2022. Additionally, there was litigation challenging CMS' co-pay accumulator policies for non-grandfathered health plans. On September 29, 2023, a federal district court vacated provisions of the 2021 Notice of Benefit and Payment Parameter ("NBPP") final rule that provided health plans with discretion whether to include manufacturer assistance toward the annual cost-sharing limit. Further, on December 22, 2023, the district court clarified that the effect of the vacatur is to reinstate the 2020 NBPP final rule, which barred the use of accumulators for brand drugs without generics. Both parties initially appealed, and subsequently withdrew their appeals. In its 2025 NBPP final rule, CMS did not address its co-pay accumulator policy and has not issued other guidance explaining its interpretation of the court's ruling, appearing to allow the 2020 policy to remain in effect. Although CMS

declined in the 2026 NBPP proposed rule to propose changes to its existing policies regarding the impact of manufacturer support on enrollee cost-sharing limits, the agency announced an intention for future rulemaking on this topic, without committing to a timeline. At the same time, however, certain states have passed laws prohibiting third-party payors from utilizing accumulator programs.

Government authorities and third-party payors also have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the U.S., the acquisition costs and reimbursement for drug products may be lower than within the U.S.

In the U.S., the decisions about reimbursement for new drug products under the Medicare program are made by CMS, an agency within HHS. CMS determines coverage standards for products reimbursed by Medicare, and private payors often adopt coverage standards established by CMS for the commercial marketplace. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor.

Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act" or the "MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs (except for those selected for negotiation under the IRA as described above), and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs, a manufacturer must enter into agreements with the Secretary of HHS to participate in the Medicaid Drug Rebate Program and the 340B drug discount program. Under the Medicaid Drug Rebate Program, manufacturers are obligated to pay rebates to the State Medicaid Programs on each unit of the manufacturer's drugs that are reimbursed by State Medicaid Programs—both with regard to Medicaid Fee for Service and Medicaid Managed Care. Additionally, under the 340B drug discount program, manufacturers extend discounts to "covered entities" eligible to participate in the 340B program, including various hospital providers. The required 340B discount on a given product is calculated based on the average manufacturer price ("AMP") and Medicaid rebate amounts reported and paid by the manufacturer under the Medicaid Drug Rebate Program. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under current law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on drugs that receive an orphan designation by the FDA. As 340B drug pricing is determined based on AMP and Medicaid rebate data, revisions to the statute and regulations governing the Medicaid Drug Rebate Program may cause the required 340B discount to increase.

Many parameters of the 340B program are subject to uncertainty. Several drug manufacturers have commenced litigation, which remains ongoing, challenging the legality of contract pharmacy arrangements, which may affect the way

in which manufacturers are required to extend the 340B Drug Discount Program prices to covered entities, including through contract pharmacies. Additionally, although HRSA historically has interpreted 340B discounts to apply only to "patients" who had their care initiated at a given 340B covered entity, a November 2023 district court ruling struck down this understanding as too narrow. Although the ruling applies only to the parties to the litigation, it introduces uncertainty as to the scope of the 340B program and may serve as a precedent for future litigation or legislation impacting the industry at large. Furthermore, in April 2026 AbbVie brought a lawsuit challenging HRSA's patient definition for purposes of the 340B Program. It is unclear whether this lawsuit will be successful and if so how it will impact our business. In another ongoing case impacting the scope of the 340B program, in November 2023, various hospitals sued HRSA to challenge an agency policy requiring that "child sites" of a hospital must be included on that hospital's most recent Medicare cost report to qualify for discounts under the program. In March 2026, the U.S. District Court for the District of Columbia struck down this policy. In 2024, several manufacturers announced an intention to adopt a "rebate model" that would offer covered entities 340B pricing through a rebate off a product's list price rather than as an up-front discount. HRSA objected to the rebate model, including by threatening to terminate the manufacturers from the 340B program. Several manufacturers filed suit against HRSA, and in May 2025 the U.S. District Court for the District of Columbia granted the government's motion for summary judgment with respect to all of the plaintiffs except for one, and granted in part the government's motion for summary judgment with respect to the remaining plaintiff. The outcome of this litigation could impact the manner in which covered entities may access 340B pricing. In addition, HRSA is soliciting comments on a 340B rebate model that it may implement in the future. Finally, it also is possible that Congress could consider other legislation that amends or reforms the 340B Drug Discount Program.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

These laws and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside of the U.S., the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union and U.K., pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes or the amount of profit made on those profits, and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Human Capital Management

As of March 31, 2026, we and our subsidiaries had approximately 721 full-time employees, including 659 in the U.S.

Our human capital objectives include sourcing, recruiting, retaining, incentivizing and developing our existing and future employees. We believe we can achieve our human capital objectives by implementing the following approaches:

- Hire high-caliber talent across all levels using both a dedicated in-house talent acquisition team and top-tier executive search firms
- Recruit multidisciplinary talent from a broad range of industries, including biopharmaceuticals, financial services, technology and consulting

- Invest in early career development through a number of important initiatives:
    - A robust Rotational Analyst ("RA") program, hiring recent college graduates from top private and public institutions
    - Partnership with Life Science Cares' Project Onramp to broaden access to early career opportunities in the life sciences
    - Partnership with Girls Who Invest to help attract and support women investors
- Offer highly competitive short- and long-term incentives through both Roivant and Vant share-based compensation programs and meaningful performance-based cash bonuses
- Undertake rigorous benchmarking analyses in partnership with third parties to ensure competitive compensation practices and conduct annual pay equity analyses to detect, analyze and remediate any compensation disparities where appropriate
- Provide company-wide training and speaker programs on topics such as unconscious bias, building trust in relationships and professional development
- Partner with external organizations to support biopharma-related initiatives in the community
- Offer a professional development stipend to each employee for use towards individual growth and development
- Unlock unique career progression across Roivant and Vants through "Vant mobility" and offer unparalleled leadership opportunities for employees through the Vant model
- Cultivate community among our employee base through Employee Resource Groups ("ERGs"), including Women@Roivant (Roivant's women's employee resource group), ROI-GBIV (Roivant's LGBTQ+ employee resource group), BIPOC (Roivant's black, indigenous and people of color employee resource group) and Asian@Roivant (Roivant's Asian American and Pacific Islander employee resource group)

In addition to these specific recruitment and retention practices above, we believe the Vant model offers significant human capital advantages. Our nimble, entrepreneurial Vants operate similarly to independent biotechnology companies where each management team, comprised of world-class drug developers and clinical operators, is solely focused on their respective Vant's mission. Our and our Vants' equity incentive plans are designed to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards to encourage focus, alignment of interests, and calculated risk-taking. As a public company, we expect to continue to hire additional personnel and to implement procedures and processes to address public company regulatory requirements and customary practices.

Corporate and Other Information

We were registered as an exempted limited company in Bermuda in 2014, under the name Valor Biotechnology Ltd. In November 2014, we changed our name to Roivant Sciences Ltd. Our principal executive offices are located at 7th Floor, 50 Broadway, London SW1H 0DB, United Kingdom. Our telephone number is +44 207 400 3347.

Our web page address is https://roivant.com. Our investor relations website is located at https://investor.roivant.com/. We will make available free of charge on our investor relations website under "SEC Filings" our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors' and officers' Section 16 Reports and any amendments to those reports after filing or furnishing such materials to the SEC. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov. References to our website do not constitute incorporation by reference of the information contained on our website, and the information contained on our website is not part of this document nor any other document that we file with or furnish to the SEC.

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 Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and the related notes, 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. References to our "product candidates" include our current product candidates 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, the creation or acquisition of healthcare technology companies and products and efforts to enforce and defend our intellectual property. We do not currently have any commercial stage products and we do not expect to generate product revenues from the commercial sale of our product candidates until we receive applicable regulatory approvals for one of our product candidates. Drug development and commercialization is a challenging and 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, including to 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 (as defined below);
- 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;

- successfully enforce and defend our intellectual property rights;

- 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 these objectives 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 interest in the Vant formed to develop 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 of a product candidate, 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 investment opportunities. A number of companies compete with us for such opportunities. These companies may possess greater financial or technical resources than we do. If we are unable to

identify a sufficient number of potential product candidates for acquisition or in-licensing, are unsuccessful in completing those acquisition or in-licensing transactions or if the product candidates that we are able to acquire or in-license do not prove to be as valuable as anticipated, we will not be able to successfully develop or receive marketing approval for those product candidates, and our business and results of operations may suffer materially as a result. Any such failure to in-license or acquire new product candidates from third parties, or the failure of those product candidates to succeed in clinical trials and eventually receive marketing approval, would have a material adverse effect on our business, financial condition, results of operations and prospects.

We 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. We do not currently have any commercial stage products and we do not expect to generate product revenues from the commercial sale of our product candidates until we receive applicable regulatory approvals for one of our product candidates. As a result, we cannot estimate with precision the extent of any future profits or losses. Since inception, we have incurred significant losses and negative cash flows from operations. As of March 31, 2026, we had cash, cash equivalents and marketable securities of approximately $4.3 billion and our accumulated deficit was approximately $501.8 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.

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 could adversely affect Immunovant's development or commercialization of IMVT-1402.

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 product candidates. Immunovant has commenced discussions with HanAll regarding the potential return to HanAll of certain rights for batoclimab.

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

Immunovant shared top-line results from the two batoclimab Phase 3 TED studies concurrently in April 2026. Neither study achieved its primary endpoint, leading Immunovant to make a decision to discontinue further development of batoclimab across all indications to focus fully on IMVT-1402. 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 plans for batoclimab. While the HanAll Agreement gives Immunovant final decision-making authority over development and regulatory matters for licensed products in Immunovant's licensed territories, and Immunovant believes it has satisfied its obligations under the HanAll Agreement, including with respect to batoclimab, HanAll may disagree with Immunovant's interpretation of the agreement or Immunovant's actions thereunder, and Immunovant may be unable to reach an agreement with HanAll regarding the future of batoclimab. This could result in a dispute with HanAll involving arbitration or litigation. In the event that HanAll asserts a breach, we and Immunovant do not believe there would be 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 could materially impact Immunovant's business. In addition, discontinuing further development of and regulatory submissions for batoclimab could impact and result in disputes with third parties, such as with respect to the contract manufacturing of batoclimab, which may be time consuming and expensive to resolve.

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

Because we have finite financial and managerial 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 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 expense 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 and certain of our Vants to operate as public companies. 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 development or commercialization 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 make us less competitive relative to our peers that operate in that manner or 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 for us and our Vants and may expose us and our Vants to increased costs that could, in turn, harm our consolidated 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 that have commercial stage products. 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 or impairment 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, and our private majority controlled subsidiary, Priovant, and may be limited in our ability to direct or control the business and the development of the product candidates or technologies at such Vants. 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. 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. 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. In addition, we may face limitations on our ability to control or direct actions at privately owned Vants in which we have minority equity partners.

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 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. For example, Eric Venker currently serves as both an executive officer of Roivant and the chief executive officer of our subsidiary, Immunovant. 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 acquisition or in-licensing transactions for our product candidates typically involve zero or low dollar-value upfront payments combined with milestone and royalty payments. These transactions 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 commercial 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 milestone and royalty payment obligations related to these products. If this were to occur, and we are not otherwise able to fund or raise the capital necessary to fund these obligations, 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.

Changes in tariffs and other governmental trade policies could negatively affect our business and results of operations.

Recent governmental actions and proposals relating to tariffs and other trade policies have created uncertainty about future trading arrangements and the possibility of jurisdictions imposing or increasing tariffs on certain goods. For example, certain governments (including the U.S. and other countries where we do business) have imposed or may impose tariffs on a wide range of products, raw materials and intermediate goods. The U.S. Supreme Court has invalidated some of the U.S. tariffs, but additional tariffs are anticipated to be imposed pursuant to the Trump Administration's ongoing U.S. trade investigation. Additional tariffs, or retaliatory measures by other countries in response, may be implemented at any time. Should these or similar tariffs remain in place (or be re-imposed or increased), or if additional tariffs or trade restrictions are enacted in the future, they could cause us or our future customers to face higher supply costs, delays or require us to switch suppliers. These actions could adversely affect our future margins, profitability, financial condition and results of operations.

In particular, 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 made and continues to make significant additional changes in U.S. trade policies and tariffs and may take actions in the future that could negatively impact U.S. trade. For example, legislation has been enacted to limit U.S. biotechnology companies from using biotechnology equipment or services produced or provided by select Chinese biotechnology companies in the performance of federal contracts or grants, 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.

In addition, the pharmaceutical industry faces specific and evolving tariff-related risks. On April 2, 2026, the United States announced significant tariffs on certain pharmaceutical products, active pharmaceutical ingredients and key starting materials. These tariffs, which were imposed pursuant to a national security investigation under Section 232 of the Trade Expansion Act of 1962, will generally go into effect in September 2026. The tariffs, which range from 10% to 100% depending on type of product and country of origin, are also subject to a number of exemptions and exclusions. There is still significant uncertainty about implementation and application of the tariffs and the exemptions and exclusions as various elements of the tariff action remain to be determined in subsequent agency actions. These new U.S. tariffs may raise costs for drug products and inputs used in our clinical development programs or that our contract manufacturers and suppliers may procure in connection with manufacturing our product candidates.

We cannot predict future changes in trade policy or the terms of any renegotiated trade agreements, nor can we determine the impact they may have on our business. Any such changes could have a material adverse effect on our business, financial condition and results of operations.

Unfavorable, uncertain and rapidly changing global and regional economic, political and public health conditions could adversely affect our business, financial condition and 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 those expenses on to our customers, in whole or in part, through price increases of product candidates following applicable regulatory approvals. 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 increased political instability, international hostilities and geopolitical tensions (such as the current conflicts between Russia and Ukraine and hostilities involving Iran, including direct military actions and proxy conflicts across the Middle East), trade disputes between nations (including trade disputes with China), a global financial crisis, wars, terrorism and civil unrest could adversely affect our business. In particular, the foregoing factors have resulted in significant volatility in global financial markets. If such volatility persists or deepens, we may be unable to access additional capital on terms that are favorable, or at all, which could negatively affect our capacity for certain strategic transactions or our ability to make other important investments. In addition, high levels of inflation and interest rate fluctuations may increase our financing costs or restrict our access to potential sources of future liquidity. Additional funds may not be available when we need them on terms that are acceptable to us. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate one or more of our product development or commercialization efforts.

Further, outbreaks of disease 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.

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 sale of our entire equity interest in our majority-owned subsidiary Dermavant Sciences Ltd. to Organon & Co. (the "Dermavant Transaction"), the consideration for which consisted of an upfront payment of $183.6 million and a milestone payment of $75 million upon FDA approval of VTAMA for the treatment of atopic dermatitis received 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 consolidated financial statements included in this Annual Report on Form 10-K.

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.

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.

In addition, 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, we may not be able to complete such 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.

We face risks associated with the use of our cash, cash equivalents and marketable securities.

As of March 31, 2026, we had cash, cash equivalents and marketable securities of $4.3 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 product candidates.

As previously disclosed, our board of directors has authorized repurchases of our common shares in an aggregate amount of up to $1.0 billion (excluding fees and expenses) (in addition to the previously disclosed common share repurchase program allowing for repurchase of our 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 twelve months ended March 31, 2026, across both repurchase authorizations, we repurchased approximately 24.0 million common shares for an aggregate repurchase price of approximately $314.9 million.

The timing and total amount of share repurchases 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. From time to time, 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.

The amount of cash available to return to shareholders, if any, may 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 a variety of factors, including market and economic conditions and volatility, political risk, tariff and trade policy, currency risk, credit risk, sovereign risk, interest rate fluctuations or other market or macroeconomic factors. Our investments consist primarily of money market funds, U.S. government securities and other debt securities, including investment-grade corporate bonds. Any fixed-income securities we hold now or in the future are subject to external factors that may adversely affect their market value or liquidity, such as interest rate and market and issuer credits risks, including actual or anticipated changes in credit ratings. Additionally, we may have balances in bank accounts that are in excess of insured deposit limits and could be subject to risks of bank failures. As a result, the value and liquidity of our cash, cash equivalents and marketable securities may fluctuate substantially. 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 face risks in the future relating to the need for additional capital to fund our operations.

Our business – including acquiring or in-licensing product candidates, running clinical trials and commercializing and marketing our product candidates following applicable regulatory approvals – is expensive and we require significant capital to fund our operations. 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 needed, 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 rely 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.

Inadequate or uncertain funding levels for the FDA, USPTO, SEC or other government agencies, including from government shut downs or significant changes in leadership personnel or policies, 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, including significant changes in leadership, personnel or policies, 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, including as recently as February 2026, 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 another funding 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.

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 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. In addition, U.S. legislation has been enacted to limit U.S. biotechnology companies from using biotechnology equipment or services produced or provided by select Chinese biotechnology companies in the performance of federal contracts or grants. 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.

Legislation targeting biotechnology companies with ties to certain foreign adversaries, including the BIOSECURE Act, could materially adversely affect our business, supply chain and results of operations.

We and certain of our Vants rely on third-party contract manufacturing organizations ("CMOs") to manufacture drug substance and drug product for our product candidates. The BIOSECURE Act, enacted in December 2025 as Section 851 of the FY2026 National Defense Authorization Act, prohibits U.S. government agencies from procuring or obtaining biotechnology equipment or services from designated "biotechnology companies of concern," and restricts agencies from entering into, extending, or renewing contracts with entities that use such covered equipment or services (the "BIOSECURE Act"). The statute relies on two designation mechanisms: (1) automatic designation through the Department of Defense's Section 1260H list of "Chinese military companies"; and (2) a criteria-based pathway administered through an interagency process led by the Office of Management and Budget, which is required to publish a list of biotechnology companies of concern within one year.

The prohibitions under the BIOSECURE Act take effect following revisions to the Federal Acquisition Regulation, with the timing depending on the basis for a company's designation as a "biotechnology company of concern." Although the statute includes a five-year rule of construction that protects legacy agreements from being invalidated by the new restrictions, a safe harbor for items no longer produced or provided by a biotechnology company of concern and limited case-by-case waivers in the national security interest, there can be no assurance that we will be able to fully avail ourselves of such provisions or that they will adequately mitigate the impact of the statute's prohibitions on our operations.

In such an event, we or our Vants may be required to transition manufacturing activities then performed by CMOs receiving the designation to alternative CMOs, which could be costly, time-consuming and disruptive to our supply chain and clinical development programs.

In addition to the BIOSECURE Act, the introduction or passage of other federal or state legislation, executive orders or regulatory actions further restricting U.S. biotechnology companies' use of certain foreign-based CMOs could impose additional constraints on our Vants' manufacturing operations and supply chain. There can be no assurance that our Vants would be able to identify and qualify alternative manufacturers on commercially reasonable terms or in a timeframe sufficient to avoid material disruption to their businesses, which could have a material adverse effect on our business, financial condition and results of 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.

We cannot provide any assurance that any clinical trials will be conducted as planned or completed on schedule, if at all. 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. The clinical trial process is also time-consuming and costly and is dependent upon collaboration with many contract research organizations ("CROs") and clinical trial sites. 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 or development of our product candidates, which could harm our ability to generate any future revenue from sales of our product candidates following regulatory approval.

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 correlate with clinical benefits sufficient to demonstrate that the efficacy endpoints of the study are met. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unobserved adverse events.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints may cause us to abandon development of the product candidate in question. For example, Immunovant's Phase 3 trials evaluating batoclimab in TED failed to meet the primary endpoint, resulting in the decision to discontinue development of batoclimab. 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 topline 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 topline 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 topline 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. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline data we previously reported. As a result, interim, preliminary and topline 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 topline 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 topline 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.

We may encounter difficulties enrolling and retaining patients in clinical trials and clinical development activities could thereby be delayed or otherwise 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 trial 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, and clinicians' and participants' perceptions of the relative advantages, risks and side effects of our product candidates compared to other available therapies, including any new drugs or treatments;
- the patient referral practices of physicians;
- our ability to obtain and maintain patient consents;
- our ability to monitor trial participants adequately during and after treatment;
- adverse results or other safety signals in our trials or related to other product candidates, and any resulting negative publicity which could discourage potential participants and their physicians from participating in our trials; 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 brepocitinib and 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.

Changes in methods of product candidate 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 completed and potentially future reductions in staff, may further increase the unpredictability in approval timelines for our product candidates. The termination of FDA employees in 2025 has been preceded and accompanied by the resignation of senior leaders within the FDA, resulting in the loss of institutional knowledge and experience. Terminations and resignations at the FDA have continued and there has been notable turnover and instability in key leadership positions. 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. Actions taken by the Trump Administration could create regulatory uncertainty for biopharmaceutical companies. Additionally,

uncertainty remains as to how the FDA's agency-wide implementation of ELSA, a generative artificial intelligence tool, including for review of drug product applications, as well as its deployment of agentic artificial intelligence capabilities, will impact the outcomes and timeliness of FDA reviews and other activities. In addition, the future of the currently applicable Prescription Drug User Fee Act construct to ensure timely FDA review of applications may be impacted due to expressed concerns about the effect on industry-FDA relations, and staffing shortages.

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 “black box” warning or contraindications on product labels or communications containing warnings, field alerts or other safety information about the product candidate to physicians, pharmacies or the public;

- 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, substantially increase the costs of commercializing any 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 make efforts to, or 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.

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. 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 any product we develop will be unrealized.

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. Further, in the U.S., we expect

that direct-to-consumer ("DTC") advertisements will be subject to increased scrutiny and enforcement by the FDA based on its aggressive enforcement posture with respect to DTC prescription drug advertisements. The FDA has also increased its scrutiny of the data used to substantiate prescription drug and biologic advertising and promotional claims more generally, which may also lead to additional industry enforcement. In the E.U. and the U.K., the promotion of prescription-only medicinal products to any audience, other than licensed healthcare professionals, is prohibited. 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. Regulators may increasingly rely on post-approval studies or real-world evidence to determine whether to maintain, modify or expand approved indications or population eligibility, which could increase costs, delay commercialization or limit the scope of approved use of our products. 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 affect 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, Priovant announced that brepocitinib received Breakthrough Therapy Designation from the FDA for the treatment of CS in May 2026 and Fast Track Designation from the FDA for the treatment of NIU in September 2024. 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. We may seek similar designations for other of our product candidates in the future where there is a basis for doing so. However, the FDA has broad discretion as to whether or not to grant such designations, so even if we believe a particular product candidate qualifies for such a designation, we cannot assure you that the FDA would decide to grant it. Further, even if our product candidates receive such a designation, the FDA may later decide that such product candidate no longer qualifies and we may not necessarily experience a faster development process, review or approval compared to conventional FDA procedures.

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.

The FDA also recently announced the Commissioner's National Priority Voucher ("CNPV") 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. 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. On October 16, 2025, the FDA announced the initial nine CNPV recipients under the program and has announced additional recipients since then.

The FDA also recently introduced the Rare Disease Evidence Principles ("RDEP") to help provide greater speed and predictability in the review of therapies intended to treat rare diseases driven by a known, in-born genetic defect with very small populations or subpopulations (generally fewer than 1,000 patients in the United States) facing progressive deterioration in function leading to rapid or significant disability or death in a relatively short period of time and for whom there are no adequate alternative therapies that alter the course of the disease. Sponsors of eligible investigational therapies intended to address the genetic defect that is the major driver of the pathophysiology for such rare disease may apply to the RDEP process prior to the launch of a pivotal trial. Approval under the process may be based on one adequate and well-controlled study together with robust confirmatory evidence and may result in additional post-marketing requirements to further ensure safety and effectiveness. The RDEP process is separate from and independent of requests for orphan drug designation discussed below and does not bear on the FDA's determination of whether a drug may be eligible for orphan drug designation. The FDA also released a plausible mechanism concept as part of its efforts to streamline and facilitate the development of rare disease and bespoke therapies for which a randomized trial is not feasible as further described in draft guidance issued in February 2026.

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 that can benefit from orphan drug market exclusivities when approved if certain conditions are met.

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. This interpretation was subsequently codified in statute by the Consolidated Appropriations Act, 2026.

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 March 2026, the E.U. institutions agreed the text of legislation constituting the reform of the E.U. regulatory framework for medicinal products (which will not apply in the U.K.). The new legislation is set to apply in full in late 2028 or late 2029. As set out above, it will 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 legislation changes the concept of unmet medical need and considers introducing additional rewards for orphan medicinal products considered to be "breakthrough orphan medicinal products" (i.e., orphan medicinal products addressing a disease with no current available medicinal treatment and which bring a clinically relevant reduction in morbidity or mortality).

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 Framework 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, EMA or MHRA can subsequently approve the same drug for a different condition or the same condition if the FDA, 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 will be modulated and likely shortened if we submit an application for marketing authorization for an orphan medicinal product after the start of full application of the new E.U. pharmaceutical legislation in late 2028 or early 2029, as discussed above.

It is also possible that current or future litigation or action by Congress could change the scope of available orphan exclusivity. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and could materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

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 the 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. The FDA under the Trump Administration has taken actions to help facilitate biosimilar development and approval. For example, the FDA issued guidances eliminating the need for data from comparative clinical efficiency studies to demonstrate biosimilarity in many circumstances as well as streamlining clinical pharmacokinetic testing when scientifically justified, each of which may accelerate biosimilar market entry. Further, the FDA has proposed amending the PHSA to no longer include a separate statutory standard for interchangeability and deem all approved biosimilars to be interchangeable, facilitating pharmacy substitution. It remains to be seen whether such a legislative amendment will be enacted.

Whether approval of a biological product qualifies for reference product exclusivity turns on whether the FDA considers 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, Priovant and Pulomvant, are currently building out focused sales, marketing and distribution infrastructure, and would expect to expand such functions, or make arrangements with third parties to perform these services, as they approach commercialization of their product candidates following regulatory approval. These Vants will also need patient support services organizations to ensure patients have appropriate access to their products, once approved.

There are significant expenses and risks involved with establishing sales, marketing and distribution capabilities, including the ability to hire, retain and appropriately incentivize qualified individuals, develop an appropriate and effective compliance function, provide adequate training to sales and marketing personnel and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development in our sales,

marketing and distribution capabilities could delay a product launch, which would adversely impact its commercialization. If the commercial launch of our product candidates, if approved, for which we recruit a sales force and establish marketing 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 our sales and marketing 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 appropriately inform and educate healthcare providers regarding the potential benefits and proper administration of our 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.

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, if approved, 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 for a product 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. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. 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.

Products approved for rare or orphan indications, such as brepocitinib if approved for dermatomyositis, may be subject to heightened public, media and legislative scrutiny with respect to their pricing. Because orphan drugs are often priced at a premium to reflect the relatively small patient populations, high unmet medical need and significant costs of development and commercialization, they have attracted particular attention from Congress, government agencies, patient advocacy groups and the press. Government authorities and third-party payors are increasingly attempting to limit or regulate drug prices and reimbursement for orphan drugs specifically. These dynamics may give rise to heightened attention and potential negative reactions to our pricing decisions for any product candidate that we commercialize, including brepocitinib, even where we believe such pricing reflects the clinical value of the therapy and the investment required to develop it. Such attention could pressure us to reduce prices, offer discounts beyond those required by law, limit our ability to negotiate adequate reimbursement rates with payors or otherwise adversely affect our ability to generate sufficient revenue to sustain commercialization of our product candidates.

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 in 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 Children's Health Insurance Program ("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 generally 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. The National Health Service expenditure on branded health service medicines is subject to a cap on permitted growth, enforced through rebate payments. However, following agreement with the US government, the U.K. government has significantly reduced the repayment rate owed by companies in 2026 under the Voluntary Scheme for Branded Medicines Pricing, Access and Growth with the intention of improving the commercial environment in the U.K. The U.K. government will update the parallel statutory scheme, which applies to companies that are not members of the voluntary scheme, to ensure broad commercial equivalence with the Voluntary Scheme. 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.

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 is pursuing various 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 reference 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 MFN price targets to manufacturers and propose a rulemaking plan to impose MFN 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 MFN lowest price. It is not clear if and how these executive orders will impact our business. This risk could arise not only from our own commercialization activities, but also from the activities of our partners, licensors or collaborators who, following regulatory approval, market our product candidates in their respective geographies at prices lower than those charged in the United States, which could be used as a reference price to impose MFN obligations and require us to lower our U.S. pricing. Furthermore, MFN pricing requirements could lead to disagreements with our partners, licensors or collaborators regarding pricing decisions, as our respective interests in setting prices in their geographies may conflict with our interest in maintaining U.S. pricing, and any such disputes could be difficult and costly to resolve and could harm our relationships with such parties.

In addition, several manufacturers have publicly announced confidential MFN agreements with the U.S., which per public Trump Administration statements would, among other things, "provide every State Medicaid program in the country access to MFN drug prices on products made by the [signing] companies"; "guarantee[] MFN prices on all new innovative medicines the [signing] companies bring to market"; "require the [signing] companies to repatriate increased foreign revenue on existing products that they realize as a result of . . . U.S. trade policies"; and require "the [signing] companies to offer medicines at a deep discount off the list price when selling directly to American patients through TrumpRx." The Trump Administration has also called on Congress to codify the Trump Administration's Most-Favored-Nation deals. It is uncertain if such legislation will be enacted, and if it is, how it could affect our business. Furthermore, in November 2025, CMS announced a new, voluntary program called the GENEROUS (GENErating cost Reductions for U.S. Medicaid) Model, under which manufacturers can offer MFN rebates to State Medicaid Programs. Also, as explained in more detail below, in December 2025, CMS issued two proposed rules related to MFN pricing. 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 some cases has caused other nations to levy reciprocal tariffs on goods manufactured in the United States.

On April 2, 2026, the United States announced significant tariffs on certain pharmaceutical products, active pharmaceutical ingredients and key starting materials. These tariffs, which were imposed pursuant to a national security investigation under Section 232 of the Trade Expansion Act of 1962, will generally go into effect in September 2026. The tariffs, which range from 10% to 100% depending on type of product and country of origin, are also subject to a number of exemptions and exclusions. There is still significant uncertainty about implementation and application of the tariffs and the exemptions and exclusions as various elements of the tariff action remain to be determined in subsequent agency actions. These new U.S. tariffs may raise costs for drug products and inputs used in our clinical development programs or that our contract manufacturers and suppliers may procure in connection with manufacturing our product candidates.

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. One notable example includes Colorado, where the state Prescription Drug Affordability Board set the first upper payment limit on a drug based on the IRA's maximum fair price. 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 November 5, 2025, CMS issued a Medicare Physician Fee Schedule final rule, which increases bona fide service fee documentation requirements, defines "bundled arrangement," addresses "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 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.

Furthermore, on December 23, 2025, CMS published two proposed rules to create new drug pricing models: the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") and the Guarding U.S. Medicare Against Rising Drug

Costs Model ("GUARD"). If finalized, these rules would require MFN pricing by requiring manufacturers to pay additional rebates for certain drugs based on the difference between the drug's Medicare price and the drug's price in market basket countries. CMS proposes that the agency would apply the new rebate requirement to utilization by approximately 25% of Medicare Part D enrollees (under GUARD) and 25% of Medicare Part B fee-for-service enrollees (under GLOBE). Assuming these proposed rules are finalized and withstand any legal challenge, it is uncertain how they could affect Roivant and its subsidiaries. Additionally, legislative proposals have been introduced in Congress that would mandate MFN pricing for particular healthcare programs if enacted. However, we cannot be certain whether any of these proposals will be enacted and if they are, how they could impact our business.

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.

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 (i) 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; (ii) 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; (iii) violations of the federal Anti-Kickback Statute; or (iv) 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.

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 the FDA. On January 5, 2024, the 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 the 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. These importation programs remain a focus of the Trump Administration. For example, executive order 14273 directed the FDA to take steps to make it easier for States to obtain approval of their import program proposals without sacrificing safety or quality. The FDA has subsequently taken steps to do so, such as offering States and Indian Tribes the opportunity to submit a draft proposal for pre-review and meet with the FDA to obtain initial feedback before formally submitting a proposal and reducing the burden in producing cost-savings analyses. 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.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles and resulting regulatory updates and changes in policy priorities.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (the "APA") "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision has had and will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the Department of Health and Human Services, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending and staffing may be significantly impacted by election cycles and legislative developments. For example, the Trump Administration has committed to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to the use of AI to review product applications. And, the recent federal government shutdown may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments may lead to greater uncertainty regarding FDA policies, slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs or other negative impacts on our business that are difficult to predict.

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 for the manufacture of our drug substance and our drug product. With respect to IMVT-1402, we have established arrangements with CMOs to supply drug substance and drug product to support our current and planned clinical trial programs, as well as anticipated commercial supply to support the potential launch of IMVT-1402, if approved. With respect to brepocitinib, as we approach potential near-term commercialization, we are working with our CMOs to scale manufacturing processes from clinical to commercial quantities. Additional 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 as well as limitations on our ability to use biotechnology equipment or services produced or provided by select Chinese biotechnology companies in the performance of federal contracts or grants. 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. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

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 the 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 the 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. 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, we face a number of related risks, including disruptions or delays in the supply of our product candidates or price fluctuations for those supplies.

In the U.S., legislative proposals and certain enacted legislation could negatively impact U.S. funding for certain biotechnology providers that have relationships with certain foreign governments or which pose a threat to national security. Currently, the potential downstream adverse impacts on entities having commercial relationships with any impacted biotechnology provider is unknown but may include supply chain disruptions or delays. If any of our suppliers become subject to any such laws, including those yet to be enacted, this may result in material delays or other disruptions to our development and, if approved, commercial activities, add significant additional cost, require that we move our non-clinical or clinical development and manufacturing activities to alternative suppliers, in each case, which may materially and adversely impact our ability to develop and manufacture our product candidates, conduct our clinical trials and, if approved, commercialize our products in a timely manner, or at all, or result in unacceptable additional costs.

If we are 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.

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, including 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 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), FcRn blockers, potential competitors to brepocitinib and IMVT-1402;

- IMAAVY (nipocalimab-aahu) and RYSTIGGO (rozanolixizumab-noli), FcRn blockers, potential competitors to IMVT-1402;

- Dazukibart, an interferon beta (IFN-beta) inhibitor, a potential competitor to brepocitinib; and

- Tyvaso (treprostinil) and Yutrepia (treprostinil), prostacyclin mimetics, potential competitors 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 the 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.

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, key employees or 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 may leave our employ 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. Negative business developments and changes in immigration laws, policies or enforcement patterns, or announcements thereof, that make it more difficult or less desirable for immigrants to work in the U.S. or introduce greater uncertainty into the immigration system and changes in immigration laws, policies or enforcement patterns, or announcements thereof, that make it more difficult or less desirable for immigrants to work in the U.S. or introduce greater uncertainty into the immigration system may make it difficult to recruit and retain qualified 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 and commercial 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 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' businesses, results of operations and financial conditions, 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.

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. We also rely on cloud-based infrastructure provided by third-party providers, including major public cloud platforms, to support key aspects of our operations. A prolonged outage, service disruption or security breach affecting one or more of these cloud providers could materially impact our ability to conduct operations, access critical data or maintain the continuity of our development programs. 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 cyberattacks, 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, cyberattacks 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. Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and other sensitive information. 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.

Cyberattacks, 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 generally must be made to affected individuals and regulatory authorities in the states where those individuals reside, and, in certain cases, also to HHS and the media. Such notices could harm our reputation and our ability to compete, and as demonstrated by other companies' experience, could trigger large class action lawsuits. 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. We are also subject to SEC rules requiring the disclosure of material cybersecurity incidents within four business days of a materiality determination, as well as annual disclosure of our cybersecurity risk management processes, strategy and governance. These rules require us to make judgments about the materiality of cybersecurity incidents, and an incorrect determination could itself expose us to securities law liability. Compliance with these disclosure obligations imposes additional operational and legal burdens on our management and may require us to publicly disclose sensitive information about our systems or incidents at a time when full information is not yet available.

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.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our privacy and data security obligations. 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 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.

Currently, 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, including those that limit the use and disclosure by "covered entities" (group health plans and most healthcare providers) of individually identifiable health information ("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 physicians, pharmacies and 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. In addition, as discussed further below, several U.S. states have enacted legislation specifically to regulate the collection, use, and disclosure of personal health information by entities not subject to the HIPAA privacy and security regulations, which requires us to invest in compliance resources and creates liability risks for us. The U.S. Department of Justice has also adopted a complex regulation that restricts, and in some cases prohibits, certain transfers of sensitive personal data to business partners located in China or other "countries of concern" with links to such designated countries. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and civil sanctions, and may result in exclusion from participation in federal and state programs.

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 harming 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.

At the state level, there are numerous laws governing the privacy and/or security of personal information. With respect to health information specifically, 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, 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.

To protect all types of personal information, various U.S. states have enacted privacy legislation in recent years and/or amended existing laws to address privacy and data security risks, including those posed by new technologies, which create additional burdens and risks for us. For example, the California Consumer Privacy Act of 2018 ("CCPA") requires 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 (which is enforceable by both the California Attorney General and the California Privacy Protection Agency) provides a private right of action for data security breaches that result in the compromise of certain sensitive personal information, increasing the likelihood of data breach litigation. Numerous other states in the United States have enacted or may seek to enact similar legislation. The U.S. federal government also contemplates federal privacy legislation from time to time.

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.-U.S. 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. It is unclear whether any legal challenges against the DPF, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful. One such challenge was already unsuccessful and the General Court of the European Union upheld the validity of the DPF by a first-instance judgment of September 3, 2025 in Case T--553/23 Latombe v Commission. This first-instance ruling is now subject to an appeal in the CJEU. 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 U.S. 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 if 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. While the GDPR and the U.K. GDPR remain substantially similar for the time being, the government of the U.K. has adopted reforms to its data privacy and cybersecurity legal framework in its Data Use and Access Act 2025, which became the law on June 19, 2025 (phasing in between June 2025 and June 2026) and will introduce significant changes from the GDPR. 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. In December 2025, the validity of the European Commission's adequacy decision in favor of the U.K. was extended until December 27, 2031, with the possibility to be further renewed. The European Commission will review the functioning of the adequacy decision after a period of four years. 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. 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.

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 our 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. 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, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and the third parties with whom we work. These AI-specific risks include, among others, model poisoning attacks in which adversaries corrupt or manipulate training data to cause AI models to produce incorrect or biased outputs, adversarial input attacks designed to manipulate model outputs in ways that are difficult to detect and model extraction attacks in which competitors or other bad actors seek to reconstruct or steal proprietary AI models by probing their outputs. These risks are of particular relevance to our drug discovery activities, where compromised AI models could undermine target identification, compound screening or other critical research processes. Furthermore, the data used to train our AI models, which may include proprietary research data, licensed third-party data or data derived from patients or clinical studies, may itself be subject to privacy regulations, third-party intellectual property claims or contractual restrictions. If our use of such training data is found to be inconsistent with applicable law, license terms or data subject rights, we could face legal claims, regulatory action, ownership disputes or restrictions on our ability to use or further develop the affected AI models. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations and adversely impact our business. The integration of AI into our and third parties' systems (potentially without the third party disclosing such use to us) subjects us to the risk that the providers of AI technologies may not meet existing or evolving legal, regulatory or industry standards relating to privacy, data protection, cybersecurity, intellectual property, product safety, human oversight or algorithmic accountability. Compliance with these requirements may require substantial investments in governance, documentation, monitoring, testing or operational controls, and may limit our ability to deploy or scale certain AI-enabled tools or features. If we do not adopt AI or other machine-learning technologies effectively or at an appropriate pace, we may also be less competitive relative to peers who do.

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.

In the United States, over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI technologies in healthcare settings. At the same time, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through an executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. Moreover, the FDA has advanced guidance and proposed frameworks for regulating AI technologies in drug discovery, marketing submissions and medical device development.

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.

The markets in which our healthcare technology and computational drug discovery Vants participate are competitive and our drug discovery efforts may not be successful in identifying new product candidates. 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 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 drug discovery efforts are centered on our discovery Vants, including PsiThera (formerly Psivant) and Covant, 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. The failure to advance these drug discovery efforts could materially affect our business, prospects, financial condition and results of operations.

Further, our computational drug discovery efforts 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.

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.

Cross-border transfers of personal data and compliance with international data protection regulations, including the GDPR, create legal and operational risks for our business.

We conduct clinical trials and other activities in the European Union and other jurisdictions that impose stringent data protection requirements. The GDPR imposes obligations with respect to the collection, storage, transfer and other processing of personal data relating to individuals in the E.U., including clinical trial participants, employees and other data subjects, and provides for fines of up to the greater of €20 million or 4% of total worldwide annual turnover for violations. The transfer of personal data from the E.U. to the U.S. and other countries is subject to specific legal mechanisms and ongoing legal uncertainty, including as a result of legal challenges to applicable transfer frameworks. In addition, the interaction between GDPR requirements and E.U. AI Act obligations, including requirements around the use of personal data in AI training and automated decision-making, creates further compliance complexity for our AI-enabled drug

discovery and clinical operations. If we or our third-party processors fail to comply with applicable data protection laws, or if the legal mechanisms on which we rely for cross-border data transfers are invalidated or become unavailable, we could face regulatory enforcement, significant fines, restrictions on our data processing activities or other adverse consequences that could materially affect our operations and development programs.

Compliance with FDA electronic records and data integrity requirements creates cybersecurity-adjacent regulatory risk that could adversely affect our business.

As a biopharmaceutical company, we are subject to FDA regulations governing electronic records and electronic signatures, including 21 CFR Part 11, as well as data integrity expectations applicable to regulated clinical and manufacturing systems. These regulations require that electronic records used in connection with FDA-regulated activities be trustworthy, reliable and generally equivalent to paper records. A cyberattack, breach, system failure or unauthorized modification affecting our regulated electronic records or systems, or those of our CROs, CMOs or other third parties conducting regulated activities on our behalf, could compromise the integrity, authenticity or availability of required records in a manner that triggers FDA scrutiny, warning letters, clinical hold or other regulatory action. Remediation of data integrity findings can be time-consuming and costly, and in severe cases could result in delays to or rejection of regulatory submissions, invalidation of clinical data, or restrictions on our operations. We may not be able to prevent all such events, and the consequences of a data integrity failure in a regulated context could be disproportionately severe relative to the underlying cybersecurity incident.

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 new E.U. Product Liability Directive (Directive (E.U.) 2024/2853), came into force on December 8, 2024 and must be transposed by the E.U. Member States into national law by December 9, 2026. The Directive will apply to products placed on the market after that date. The new Directive modernizes the European product liability regime to address technological advancements, including AI-enabled devices, standalone software, continuous learning systems, cybersecurity risks and circular-economy business models. Importantly, whereas historically product liability claims were difficult for plaintiffs to prove in the E.U., the new Directive has been drafted with the intention of rebalancing the apportionment of risk in favor of plaintiffs.

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 occurs that prevents us from using all or a significant portion of our offices, that damages critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupts 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 if it reaches an EEA/U.K.-audience and could trigger enforcement and penalties. This is an area of increased scrutiny in both the EEA and the U.K.and trigger enforcements and penalties. This is an area of increased scrutiny in both the EEA and the U.K.

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, and we are not granted any patent term extension, 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 owned 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.

For example, certain U.S. patents relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH ("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 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. 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, 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 right to enforce patent rights against third party infringers under the license 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 covering IMVT-1402 and batoclimab from HanAll. We and Immunovant depend, and will continue to depend, on the HanAll Agreement for the rights to develop, manufacture and commercialize certain product candidates. If, for any reason, the rights granted to Immunovant under the HanAll Agreement are terminated or Immunovant otherwise loses those rights, it would adversely affect our and Immunovant's business. The HanAll Agreement also imposes, and any future collaboration agreements or license agreement we enter into are likely to impose, various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us or our Vants. For more information regarding the risks associated with the HanAll Agreement, please see the risk factor above entitled "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."

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 Roivant's 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 certain patents, including U.S. Patent Nos. 8,492,359, 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 2025, GSG and Arbutus filed five international lawsuits against Moderna targeting alleged infringing activity with respect to Moderna's vaccine for COVID-19 in 30 countries (the "Moderna International Cases"). On March 3, 2026, GSG and, solely for certain purposes, Genevant, and Arbutus entered into a settlement agreement with Moderna Inc. and Moderna TX, Inc. (the "Settlement Agreement") to resolve the Moderna Action and the Moderna International Cases. Under the Settlement Agreement, Moderna agreed to make a $950 million noncontingent lump sum payment to GSG and Arbutus on or before July 8, 2026. In addition, as described in more detail below, Moderna agreed to make an additional contingent lump sum payment of up to $1.3 billion (the "Contingent Payment") to GSG and Arbutus, depending on the outcome of Moderna's appeal of the District Court's rejection of Moderna's affirmative defense under 28 U.S.C. § 1498 ("§ 1498"). In March 2026, Moderna filed a notice of its appeal (the "§ 1498 Appeal") with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit"). Briefing of the § 1498 Appeal is expected to be completed in July 2026, with oral arguments before the Federal Circuit expected to take place in 2027.

Under the terms of the Settlement Agreement, Moderna will make the Contingent Payment to GSG and Arbutus (i) if the Federal Circuit affirms, or if there is a final non-appealable judgment that affirms, the rejection of Moderna's affirmative defense pursuant to § 1498 by the District Court in its entirety or otherwise holds that § 1498 does not bar GSG's and Arbutus's claim against Moderna as to either or both of direct infringement and indirect infringement with respect to all of the doses subject to Moderna's appeal, or (ii) upon a voluntary dismissal of Moderna's appeal (any of the foregoing under (i) or (ii), a "GSG/Arbutus § 1498 Victory").

The receipt of the Contingent Payment is subject to a number of risks and uncertainties that could impact the amount and timing of any proceeds received by GSG and Arbutus. If the Federal Circuit determines that § 1498 bars GSG's and Arbutus's direct and indirect infringement claims with respect to all doses subject to Moderna's appeal, no Contingent Payment will be owed to GSG and Arbutus. If § 1498 is found to bar claims only with respect to some of such doses, the Contingent Payment will be prorated and the precise amount of the Contingent Payment could be subject to dispute if the Federal Circuit's ruling does not clearly articulate the number of affected doses, potentially requiring binding arbitration to resolve. We cannot predict the timing or outcome of the § 1498 Appeal. Even if GSG and Arbutus receive the Contingent Payment following a favorable appellate outcome, as described above, GSG and Arbutus would be required to return the Contingent Payment to Moderna, plus interest, if the favorable outcome were to be subsequently overturned in Moderna's favor in a final non-appealable decision. The obligation to potentially return the Contingent Payment, together with interest, could have a material adverse effect on our consolidated financial condition if such a repayment obligation were to arise after the proceeds are deployed or distributed.

More broadly, litigation settlement agreements involve inherent risks and uncertainties. For example, Moderna could default on, or otherwise fail to make, the Contingent Payment under certain circumstances. In addition, the terms of the Settlement Agreement represent a final resolution of the Moderna Action and the Moderna International Cases. GSG and Arbutus will have no further ability to seek additional damages from Moderna in connection with the licensed products and activities covered by the Settlement Agreement, even if circumstances change or additional infringing activities are discovered that fall within the scope of the license. The mutual releases contained in the Settlement Agreement extinguish claims that might otherwise have been available to GSG and Arbutus. In addition, the Settlement Agreement resolves only

the disputes between GSG and Arbutus, on the one hand, and Moderna and its affiliates, on the other, and does not affect other pending litigation, including the Pfizer Action described below, which remains ongoing and subject to its own risks and uncertainties.

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. In September 2025, the court issued its claim construction ruling, which construed the disputed claim terms in a manner that GSG generally considers to be favorable.

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 Pfizer Action, will ultimately be resolved successfully. In particular, there is no assurance that the resolution of the Moderna Action will be predictive of the outcome of the Pfizer Action. 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 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 IMVT Corp. 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. Any waiver of our patent or other intellectual property protection by the U.S. and other foreign governments, including with respect to GSG'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 or to challenge the patentability, validity or enforceability of patents owned by other parties. For example, the USPTO Director has recently exercised discretionary authority to raise the threshold for instituting IPR and other post-grant proceedings, which may make it more difficult for parties like us to challenge the patentability of patents owned or controlled by competitors through these proceedings. 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 party's 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 and may not obtain 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 agreements, 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. Even if such agreements are in place, a court may find the agreements or certain provisions to be unenforceable or may limit their scope or duration in ways that fail to fully protect our trade secrets, proprietary software, technology, processes and other confidential information. Furthermore, 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 such information, 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.

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 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.

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. For example, certain proprietary information, trade secrets or other confidential data may be uploaded to or processed by third-party AI platforms without our authorization or in violation of our policies, and we cannot assure that such platforms will maintain the confidentiality of any information submitted to them or that such information will not be used to train AI models, disclosed to third parties or accessed by unauthorized users, any of which could result in the loss of trade secret status or other competitive harm. 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.

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.

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.

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 us;
- 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.

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

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

Although we have determined that our internal control over financial reporting was effective as of March 31, 2026, 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 and 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.

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 (the "evergreen increase"). In February 2026, our board of directors approved an evergreen increase for the fiscal year ending March 31, 2026, resulting in the number of shares available for issuance under the 2021 EIP plan increasing by an amount representing 5% of the common shares outstanding as of March 31, 2025 (having previously deferred this decision from March 31, 2025). The issuance of securities pursuant to this or future evergreen increases may result in additional dilution for our shareholders, potentially causing our share price to 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 our 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.

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.

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 any of our product candidates receives approval by applicable regulatory bodies, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions where such approvals have been granted, in part through intercompany service agreements between our subsidiaries and us. In that case, we anticipate that 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 and determinations are not binding on applicable taxing authorities. If taxing authorities in any jurisdiction were to successfully challenge our transfer pricing procedures and determinations as not reflecting arm's length transactions between two or more affiliated companies, they could require such affiliated companies to adjust their transfer pricing procedures and determinations and thereby could require us to 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 jurisdiction from which the income is reallocated does not agree with the reallocation, both jurisdictions 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 could increase our 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 an ultimate tax determination is uncertain. As such, there can be no assurance that the relevant tax authorities will not assert that the actual tax treatment of such transactions differs from the intended tax treatment. As we 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 jurisdictions 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 global tax authorities (including the U.K., Switzerland, the U.S., Bermuda and other jurisdictions), as well as being affected by certain changes 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: (i) the jurisdictions in which profits are determined to be earned and taxed; (ii) the resolution of issues arising from any future tax audits with various tax authorities; (iii) changes in the valuation of our deferred tax assets and liabilities; (iv) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (v) changes in the taxation of stock-based compensation; (vi) 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; (vii) challenges to the transfer pricing policies related to our structure; (viii) potential taxation under the OECD BEPS 2.0; and (ix) 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 (i) the total combined voting power of all classes of stock of such corporation entitled to vote or (ii) 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 January 1, 2026, a portion of the CFC's "global intangible low-taxed income" (commonly known as "GILTI"). The One Big Beautiful Bill Act provides for certain changes to this regime 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, 2026. 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, 2026 because our U.S. subsidiaries are treated as constructively owning the stock of such non-U.S. subsidiaries pursuant to a "downward attribution" rule (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 in the case of taxable years to which the One Big Beautiful Bill Act applies) 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, 2026, 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, 2026, 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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

Roivant's corporate information security organization, led by our Chief Information Officer ("CIO"), is responsible for the overall information security strategy, policy, security engineering, operations and cybersecurity threat and incident detection and response centrally at Roivant and the majority of our Vants. Certain of our Vants, including Immunovant and our healthcare technology Vants, have established and maintain separate cybersecurity functions which are similarly designed to protect their information and assets from cybersecurity threats or incidents.

Roivant and the Vants' information security organization manages a robust enterprise security structure with the goal of preventing and mitigating any cybersecurity incidents, while simultaneously working to continually increase information technology system resilience designed to minimize any business impact should a cybersecurity incident occur. Central to Roivant's information security organization is our Cybersecurity Incident Response Team, which is responsible for the protection, detection and response capabilities used to protect our data and enterprise computing networks. The Cybersecurity Incident Response Team comprises members of our IT Security Operations function and is supported by third-party security partners providing managed detection, response and forensic capabilities. A Cybersecurity Steering Committee provides cross-functional leadership input and alignment for the cybersecurity program, ensuring security initiatives reflect organizational risk tolerance and business priorities and is responsible for escalating cybersecurity threats and incidents based on a defined severity framework. Threats and incidents assessed as having a moderate or higher potential business impact are escalated to senior management and reported to the Audit Committee of the board of directors.

Roivant and the Vants implement multiple levels of cybersecurity measures, including standard malware detection and prevention software, email security programs, vulnerability detection and remediation software, security patching management, security event logging and reviews and special isolation and access controls for data repositories that may contain sensitive information, including protected health information.

Roivant and the Vants' cybersecurity programs are informed by recognized industry frameworks, including the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF), and are designed to identify, protect against, detect, respond to and recover from cybersecurity threats. Our programs include periodic risk assessments and security testing supported by cybersecurity technologies, including third-party security solutions and vulnerability management and monitoring tools, designed to monitor, identify and manage risks from cybersecurity threats and incidents. Where applicable, our healthcare technology Vants maintain additional controls deisgned to align with HIPAA

security requirements and other healthcare-specific regulatory obligations. In addition, we have implemented employee security and awareness training related to cybersecurity threats and incidents.

Roivant and the Vants undergo periodic internal compliance audits and external reviews to evaluate our controls, including cybersecurity controls. Additionally, a majority of our information technology systems are built on services provided by third parties. We operate a vendor risk management program under which third-party suppliers with access to our systems or data are assessed based on the sensitivity of the data or systems they access and the nature of their services. This tiered approach includes security assessments of vendor infrastructure, review of relevant certifications (such as SOC 2 Type II reports), and targeted questionnaires addressing specific risk areas, including the use and security of AI products. Vendors are subject to reassessment upon material changes to their services or upon identification of new risk factors. Findings from these assessments are reviewed by our information security organization and escalated as appropriate. Our control over and ability to monitor the security posture of third parties with whom we do business remains limited and there can be no assurance that we can prevent, mitigate or remediate the risk of any compromise or failure in the security infrastructure owned or controlled by such third parties. Additionally, any contractual protections with such third parties, including our right to indemnification, if any at all, may be limited or insufficient to prevent a negative impact on our business from any such compromise or failure.

During the fiscal year we did not experience any cybersecurity incidents that were determined to be material to our business, results of operations or financial condition. No previously reported cybersecurity incidents continue to have a material impact on the Company.

Governance Related to Cybersecurity Risks

Roivant's board of directors oversees our overall risk management strategy, including with respect to cybersecurity risks. Cybersecurity risk management policies and procedures are integrated into our overall risk management strategy, which is overseen by the audit committee of the board of directors ("Audit Committee"). At least annually, the Audit Committee receives a comprehensive briefing from our CIO covering our information security posture, key risk indicators, results of internal and external audits, and the status of ongoing cybersecurity initiatives. In addition, management provides updates to the Audit Committee on an as-needed basis when significant cybersecurity developments arise between scheduled reviews. The board of directors as a whole is informed of material cybersecurity matters through regular reporting from the Audit Committee.

At the management level, our CIO is primarily responsible for leading our cybersecurity strategy centrally at Roivant and the majority of our Vants. Our CIO has over 20 years of experience in information technology across biotechnology and other industries, holds a Bachelor of Science in Management Information Systems and an MBA in International Business. We also maintain a Security Operations team of experienced senior-level engineers who design, implement and operate our information technology ecosystem, helping to implement cybersecurity best practices throughout our infrastructure and governance processes. Members of this SecOps team have relevant security certifications including Certified Information Security Manager ("CISM").

At Immunovant and the healthcare technology Vants that have established and maintain separate cybersecurity functions, governance is similarly overseen in the first instance by the boards of directors of those Vants as part of their overall risk management strategy, with ultimate oversight on a company-wide basis by the Roivant board of directors.

ITEM 2. PROPERTIES

Our principal executive offices are located at 7th Floor, 50 Broadway, London SW1H 0DB, United Kingdom. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda.

Our subsidiary Roivant Sciences, Inc. ("RSI") leases 54,702 square feet of office space located in New York, New York, pursuant to a lease agreement (the "RSI Lease Agreement") with One Penn Plaza LLC that expires in August 2041. The RSI Lease Agreement contains an option to early terminate in August 2036 and an option to extend the term for one additional period of five years or 10 years at then-market rates in August 2041. We do not own any properties.

We believe that our subsidiaries' leased facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

ITEM 3. 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 any 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 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common shares are listed on The Nasdaq Global Select Market under the symbol "ROIV."

Holders

As of May 12, 2026, there were 48 holders of record of our common shares. The actual number of holders of our common shares is greater than this number of record holders and includes shareholders who are beneficial owners but whose common shares are held in street name by banks, brokers and other nominees.

Dividend Policy

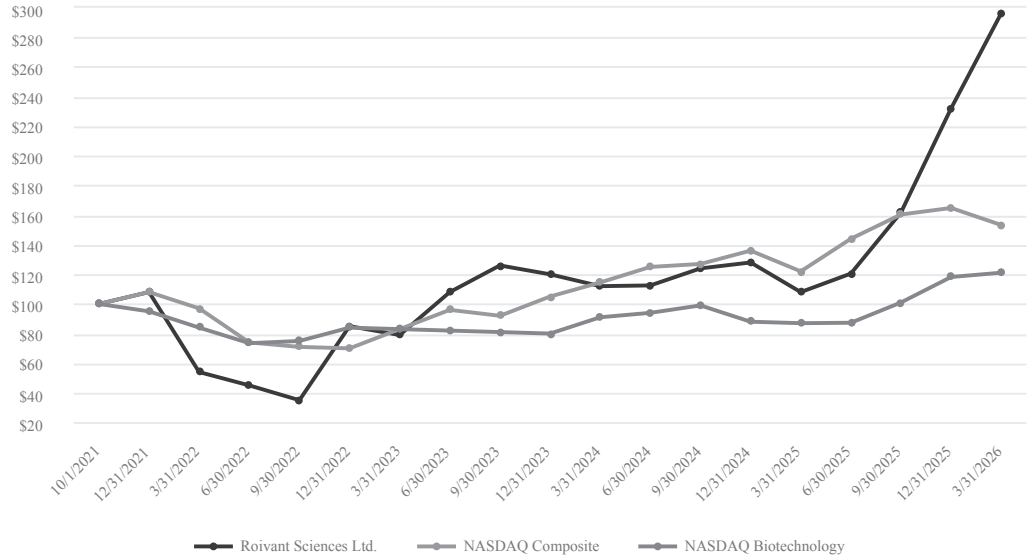
We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated herein by reference.

Performance Graph

The following stock performance graph illustrates a comparison from October 1, 2021 (the date our common shares commenced trading on The Nasdaq Global Market) through March 31, 2026, of the total cumulative shareholder return on our common shares, The Nasdaq Composite Index and The Nasdaq Biotechnology Index. This graph assumes an initial investment of $100 on October 1, 2021 at the market closing price of $9.35 per share, and that all dividends were reinvested (although dividends have not been paid on our common shares). The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common shares.



The information included under the heading Performance Graph is "furnished" and not "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be "soliciting material" subject to Regulation 14A or incorporated by reference in any filing under the Securities Act or the Exchange Act.

Sales of Unregistered Securities and Use of Proceeds

None.

Issuer Repurchases of Equity Securities

During the three and twelve months ended March 31, 2026, we repurchased 3,956,362 and 23,955,812 common shares, respectively, for $109.7 million and $314.9 million, respectively. As of March 31, 2026, we were authorized to repurchase up to $890.3 million of our common shares.

The following table summarizes our common share repurchase transactions for the three months ended March 31, 2026:

Period	Total Number of Common Shares Purchased[1]	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Program[1][2]	Approximate Dollar Value of Common Shares that May Yet Be Purchased Under the Program[2]
				(in millions)
January 1 – 31, 2026	261,945	$ 21.29	261,945	$ 494.4
February 1 – 28, 2026	158,510	$ 21.32	158,510	$ 491.0
March 1 – 31, 2026	3,535,907	$ 28.50	3,535,907	$ 890.3
Total	3,956,362		3,956,362	

(1) The total number of common shares purchased set forth in this column is based on the trade date of the repurchase transaction (not the settlement date of the repurchase transaction).

(2) On April 2, 2024, we announced that our board of directors had authorized a common share repurchase program, allowing for repurchases of Roivant common shares in an aggregate amount of up to $1.5 billion (excluding fees and expenses). This share repurchase program was fully exhausted as of June 30, 2025. On June 25, 2025, we announced that our board of directors had authorized up to $500 million (excluding fees and expenses) in additional common share repurchases. On March 3, 2026, we announced that our board of directors authorized a further $500 million (excluding fees and expenses) in additional common share repurchases (in addition to the previously announced $500 million repurchase authorization from June 2025 and the $1.5 billion repurchase authorization from April 2024). The timing and total amount of common shares repurchased depends on several factors, including the market price of our common shares, general business, macroeconomic and market conditions and other investment opportunities. Share repurchases 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. Please refer to Note 8, "Shareholders' Equity" to Roivant's consolidated financial statements included in this Annual Report on Form 10-K for additional information related to share repurchases. The table excludes fees and commissions payable in connection with common share repurchases.

* In addition to the repurchase transactions set forth above, during the fiscal year ended March 31, 2026, we withheld 25,795,468 common shares associated with net share settlements to cover (i) tax withholding obligations upon the vesting and settlement of equity incentive awards issued under our equity incentive plans, including RSUs and CVARs and (ii) the payment of the exercise price of certain stock options.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of Roivant's financial condition and results of operations should be read in conjunction with Roivant's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on 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 Annual Report on Form 10-K. 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 JAK1 and TYK2 currently under review at the FDA for the treatment of dermatomyositis and also in late stage development for the treatment of non-infectious uveitis, cutaneous sarcoidosis and lichen planopilaris; IMVT-1402, a fully human monoclonal antibody 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.

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 with additional studies 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. In July 2025, the Compensation Committee also approved a multi-year incentive compensation program for Frank Torti in connection with his appointment as an executive officer of the Company. Collectively, these compensation arrangements are referred to herein as the "Senior Executive Compensation Program." The long-term equity incentive awards granted pursuant to this program will continue to 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 audited 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 sale of our entire equity interest in our majority-owned subsidiary, Telavant Holdings, Inc. ("Telavant"), to Roche Holdings, Inc. ("Roche") in December 2023 (the "Roche Transaction") as well as a gain resulting from the achievement of a one-time milestone in June 2024. In December 2023, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately $7.1 billion in cash at the closing of the Roche Transaction and a one-time milestone payment of $150 million in cash, paid in August 2024 following the initiation of a Phase 3 trial in UC. Prior to the Roche Transaction, we held 75% of the issued and outstanding shares of common stock and preferred stock of Telavant, and Pfizer Inc. ("Pfizer") owned the remaining 25%, in each case on an as-converted basis. The $7.1 billion in closing consideration and $150 million one-time milestone payment were paid to all of Telavant's equity holders, including holders of Telavant restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction. We recognized a gain on sale of Telavant net assets of $110.4 million for our pro rata portion of the one-time milestone consideration during the year ended March 31, 2025 and approximately $5.3 billion for the sale of our entire equity interest in Telavant during the year ended March 31, 2024. Refer to Note 5, "Recent Transactions and Developments" of our audited financial statements for further information regarding the Roche Transaction.

Gain on litigation settlement

Gain on litigation settlement reflects a gain resulting from the settlement agreement (the "Settlement Agreement") entered between our subsidiary, Genevant Sciences GmbH ("Genevant"), Arbutus Biopharma Corporation (together with Genevant, "Genevant/Arbutus"), and, solely for certain purposes, Genevant's parent Genevant Sciences Ltd., and Moderna, Inc. and ModernaTx, Inc. (together, "Moderna") in March 2026 to resolve all patent infringement litigation between Genevant/Arbutus and Moderna pending in the U.S. and internationally relating to Moderna's unauthorized use of Genevant/Arbutus' lipid nanoparticle ("LNP") delivery technology in its vaccines, including SPIKEVAX. We recognized a gain on litigation settlement of $770.2 million during the year ended March 31, 2026 in the accompanying consolidated statements of operations for Genevant's expected portion of the $950 million non-contingent, non-creditable, and non-refundable payment to be made by Moderna to Genevant and Arbutus on or before July 8, 2026 (the "Fixed Payment"). The allocation of this Fixed Payment is subject to adjustment upon final determination of actual litigation costs and expenses incurred. Refer to Note 5, "Recent Transactions and Developments" of our audited financial statements for further information regarding the Settlement Agreement.

Change in fair value of investments

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

Change in fair value of liability instruments

Change in fair value of liability instruments primarily includes the loss (gain) relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including the earn-out share liabilities (prior to vesting) (the "Earn-Out Shares") and warrant liabilities (prior to their redemption) issued in connection with our business combination (the "Business Combination") with Montes Archimedes Acquisition Corp. ("MAAC"), a special purpose acquisition company. Refer to Note 13, "Earn-Out Shares, Public Warrants and Private Placement Warrants" of our audited financial statements for further information regarding the redemption of our warrants.

Gain on deconsolidation of subsidiaries

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

Interest income

Interest income consists of interest earned on our cash equivalents 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 (loss) from discontinued operations, net of tax

Income (loss) from discontinued operations, net of tax consists of the gain on sale of subsidiary interests for the year ended March 31, 2025 resulting from the sale of our entire equity interest in our majority-owned subsidiary, Dermavant Sciences Ltd. ("Dermavant"), to Organon & Co. ("Organon") in October 2024 (the "Dermavant Transaction") and the financial results of Dermavant through the closing of the Dermavant Transaction. Refer to Note 6, "Discontinued Operations" of our audited 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 years ended March 31, 2026, 2025 and 2024

The following table sets forth our results of operations for the years ended March 31, 2026, 2025 and 2024:

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Revenue	$ 8,260	$ 29,053	$ 32,713	$ (20,793)	$ (3,660)
Operating expenses:					
Cost of revenues	1,285	911	1,599	374	(688)
Research and development	681,812	550,413	439,909	131,399	110,504
Acquired in-process research and development	—	—	26,450	—	(26,450)
General and administrative	610,466	591,410	416,133	19,056	175,277
Total operating expenses	1,293,563	1,142,734	884,091	150,829	258,643
Gain on sale of Telavant net assets	—	110,387	5,348,410	(110,387)	(5,238,023)
Gain on litigation settlement	770,235	—	—	770,235	—
(Loss) income from operations	(515,068)	(1,003,294)	4,497,032	488,226	(5,500,326)
Change in fair value of investments	(105,046)	(55,186)	47,973	(49,860)	(103,159)
Change in fair value of liability instruments	47,704	(15,756)	46,838	63,460	(62,594)
Gain on deconsolidation of subsidiaries	(11,027)	(3,108)	(32,772)	(7,919)	29,664
Interest income	(178,109)	(258,375)	(146,425)	80,266	(111,950)
Other (income) expense, net	(4,012)	10,721	13,562	(14,733)	(2,841)
(Loss) income from continuing operations before income taxes	(264,578)	(681,590)	4,567,856	417,012	(5,249,446)
Income tax expense	133,329	48,174	21,503	85,155	26,671
(Loss) income from continuing operations, net of tax	(397,907)	(729,764)	4,546,353	331,857	(5,276,117)
Income (loss) from discontinued operations, net of tax	—	373,030	(315,147)	(373,030)	688,177
Net (loss) income	(397,907)	(356,734)	4,231,206	(41,173)	(4,587,940)
Net loss attributable to noncontrolling interests	(98,136)	(184,753)	(117,720)	86,617	(67,033)
Net (loss) income attributable to Roivant Sciences Ltd.	$(299,771)	$ (171,981)	$4,348,926	$ (127,790)	$(4,520,907)

Variance analysis for years ended March 31, 2026, 2025 and 2024

Revenue

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Revenue	$ 8,260	$ 29,053	$ 32,713	$ (20,793)	$ (3,660)

Revenue decreased by $20.8 million to $8.3 million for the year ended March 31, 2026, compared to $29.1 million for the year ended March 31, 2025. Revenue decreased by $3.7 million to $29.1 million for the year ended March 31, 2025, compared to $32.7 million for the year ended March 31, 2024. During the years ended March 31, 2026, 2025 and 2024, revenue was primarily driven by amounts earned in connection with license agreements at Genevant.

Research and development expenses

For the years ended March 31, 2026, 2025 and 2024, our research and development expenses consisted of the following:

	Years Ended March 31,			Change	
	2026	2025	2024[1]	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Program-specific costs:					
Anti-FcRn franchise—endocrine diseases	$ 90,359	$ 63,073	$ 33,205	$ 27,286	$ 29,868
Anti-FcRn franchise—neurological diseases	82,515	93,224	41,060	(10,709)	52,164
Anti-FcRn franchise—rheumatology diseases	48,813	23,897	—	24,916	23,897
Anti-FcRn franchise—dermatology diseases	20,264	15,633	—	4,631	15,633
Anti-FcRn franchise—other clinical and nonclinical	3,367	9,327	39,811	(5,960)	(30,484)
Anti-FcRn franchise—contractual costs related to batoclimab program discontinuation	38,952	—	—	38,952	—
Brepocitinib	60,272	45,125	38,563	15,147	6,562
Mosliciguat	36,077	19,746	4,307	16,331	15,439
RVT-3101	—	—	35,129	—	(35,129)
Other development and discovery programs[2]	48,251	57,729	57,141	(9,478)	588
Total program-specific costs	428,870	327,754	249,216	101,116	78,538
Unallocated internal costs:					
Share-based compensation	47,867	39,780	32,400	8,087	7,380
Personnel-related expenses	167,790	146,162	123,283	21,628	22,879
Other expenses	37,285	36,717	35,010	568	1,707
Total research and development expenses	$ 681,812	$ 550,413	$ 439,909	$ 131,399	$ 110,504

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

[2] For the year ended March 31, 2026, included terminated program expenses of $1.9 million for namilumab. For the year ended March 31, 2025, included terminated program expenses of $12.7 million for namilumab and $1.9 million for RVT-2001. For the year ended March 31, 2024, included terminated program expenses of $13.2 million for namilumab and $10.1 million for RVT-2001.

Research and development expenses increased by $131.4 million to $681.8 million for the year ended March 31, 2026, compared to $550.4 million for the year ended March 31, 2025. This increase was primarily driven by an increase in program-specific costs of $101.1 million, personnel-related expenses of $21.6 million and share-based compensation of $8.1 million.

The increase of $101.1 million in program-specific costs was primarily driven by increases of $79.1 million related to the anti-FcRn franchise (of which $39.0 million related to contractual costs recognized in connection with the discontinuation of batoclimab), $16.3 million related to mosliciguat and $15.1 million related to brepocitinib.

The increase of $21.6 million in personnel-related expenses, which is an unallocated internal cost, was primarily driven by higher headcount to support additional clinical studies for the anti-FcRn franchise activities at Immunovant and brepocitinib at Priovant. The $8.1 million increase in share-based compensation expense was primarily driven by the Priovant Exchange Offer. Refer to Note 9, “Share-Based Compensation and Other Compensation Plans” of our financial statements for further details.

Research and development expenses increased by $110.5 million to $550.4 million for the year ended March 31, 2025, compared to $439.9 million for the year ended March 31, 2024. This increase was primarily driven by increases in program-specific costs of $78.5 million, personnel-related expenses of $22.9 million, share-based compensation of $7.4 million and other expenses of $1.7 million.

The increase of $78.5 million in program-specific costs was primarily driven by increases of $91.1 million related to the anti-FcRn franchise, reflecting the progression of our programs, and $15.4 million related to mosliciguat, which was acquired during the year ended March 31, 2024. These increases were partially offset by a decrease in expense of $35.1 million related to RVT-3101, which was sold to Roche in December 2023.

The increase of $22.9 million in personnel-related expenses was primarily driven by higher personnel-related expenses at Immunovant as a result of higher headcount and enhancement of capabilities to support Immunovant's strategic objectives as clinical activities progress. Included in personnel-related expenses is a special one-time cash retention bonus award granted to employees in December 2023 (the "Cash Bonus Program"). During the years ended March 31, 2025 and 2024, we recognized additional research and development expense of $5.8 million and $9.9 million, respectively, relating to the Cash Bonus Program.

Acquired in-process research and development expenses

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
Acquired in-process research and development expenses	$ —	$ —	$ 26,450	$ —	$ (26,450)

There were no acquired in-process research and development expenses for the years ended March 31, 2026 and 2025. Acquired in-process research and development expenses of $26.5 million for the year ended March 31, 2024 was driven by $14.0 million of consideration for the purchase of IPR&D relating to the asset acquisition of mosliciguat completed by our subsidiary, Pulmovant, Inc. ("Pulmovant") and $12.5 million relating to the achievement of development and regulatory milestones for batoclimab.

General and administrative expenses

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
General and administrative expenses	$ 610,466	$ 591,410	$ 416,133	$ 19,056	$ 175,277

General and administrative expenses increased by $19.1 million to $610.5 million for the year ended March 31, 2026, compared to $591.4 million for the year ended March 31, 2025. This increase was primarily due to an increase in share-based compensation expense of $58.8 million, primarily due to the long-term equity incentive awards from the Senior Executive Compensation Program and incremental share-based compensation expense resulting from the Priovant Exchange Offer, an impairment loss of $17.1 million related to the relocation of the U.S. corporate headquarters of Roivant Sciences, Inc. and an increase of $9.1 million in professional fees, reflecting higher litigation-related costs incurred. These increases were partially offset by a decrease of $69.9 million in personnel-related expense, which largely resulted from higher expense for the year ended March 31, 2025 related to the one-time cash retention awards from the Senior Executive Compensation Program and the Cash Bonus Program (as defined below).

General and administrative expenses increased by $175.3 million to $591.4 million for the year ended March 31, 2025, compared to $416.1 million for the year ended March 31, 2024. This increase was primarily due to increases in share-based compensation expense of $84.6 million and personnel-related expenses of $79.6 million, largely as a result of long-term equity and one-time cash retention awards from the Senior Executive Compensation Program. Refer to Note 9, "Share-Based Compensation and Other Compensation Plans" of our audited financial statements for further information.

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

	Years Ended March 31,			Remaining Expense as of March 31,
	2026	2025	2024	2026
	(in thousands)			
Cash Bonus Program	$ 4,510	$ 21,209	$ 35,628	$ —
Senior Executive Compensation Program:				
Cash awards	14,819	86,421	—	—
Performance restricted stock units	139,374	82,186	—	141,773
Restricted stock units	13,457	6,410	—	52,859
Stock options	725	640	—	1,567
Total	$ 172,885	$ 196,866	$ 35,628	$ 196,199

Gain on sale of Telavant net assets

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Gain on sale of Telavant net assets	$ —	$ 110,387	$ 5,348,410	$ (110,387)	$ (5,238,023)

Gain on sale of Telavant net assets was $110.4 million for the year ended March 31, 2025 and $5.3 billion for the year ended March 31, 2024. The gain for the year ended March 31, 2025 resulted from the achievement of a one-time milestone in June 2024. The gain for the year ended March 31, 2024 resulted from the sale of our entire equity interest in Telavant to Roche in December 2023. Refer to Note 5, "Recent Transactions and Developments" of our audited financial statements for further information.

Gain on litigation settlement

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Gain on litigation settlement	$ 770,235	$ —	$ —	$ 770,235	$ —

Gain on litigation settlement was $770.2 million for the year ended March 31, 2026 and reflects Genevant's expected portion of the Fixed Payment to be made by Moderna to Genevant and Arbutus as a result of the Settlement Agreement entered in March 2026. The allocation of this Fixed Payment is subject to adjustment upon final determination of actual litigation costs and expenses incurred. Refer to Note 5, "Recent Transactions and Developments" of our audited financial statements for further information.

Change in fair value of investments

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
	(in thousands)				
Change in fair value of investments	$ (105,046)	$ (55,186)	$ 47,973	$ (49,860)	$ (103,159)

Change in fair value of investments were unrealized gains of $105.0 million and $55.2 million for the years ended March 31, 2026 and 2025, respectively. The change of $49.9 million was primarily driven by changes in the public share price of Arbutus, as well as the change in fair value of our investment in Datavant, which was driven by growth in forecasted financial performance.

Change in fair value of investments was an unrealized gain of $55.2 million and an unrealized loss of $48.0 million for the years ended March 31, 2025 and 2024, respectively. The change of $103.2 million was primarily driven by changes in the public share price of Arbutus, as well as the change in the fair value of our investment in Datavant. Refer to Note 4, "Equity Method Investments" of our audited financial statements for further information.

Change in fair value of liability instruments

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
Change in fair value of liability instruments	$ 47,704	$ (15,756)	$ 46,838	$ 63,460	$ (62,594)

Change in fair value of liability instruments was a loss of $47.7 million, a gain of $15.8 million and a loss of $46.8 million for the years ended March 31, 2026, 2025 and 2024, respectively. The change in fair value of liability instruments for the year ended March 31, 2026 consisted of a loss relating to the Earn-Out Shares issued as part of the Business Combination. The Earn-Out Shares vested during the year ended March 31, 2026. Accordingly, the Earn-Out Shares were remeasured upon their vesting, and these final remeasurements were recognized in the change in fair value of liability instruments. No further liability remains related to the Earn-Out shares.

Change in fair value of liability instruments for the year ended March 31, 2025 primarily consisted of a gain relating to the Earn-Out Shares issued as part of the Business Combination. Change in fair value of liability instruments for the year ended March 31, 2024 primarily consisted of losses relating to the warrants and Earn-Out Shares issued as part of the Business Combination. Refer to Note 13, "Earn-Out Shares, Public Warrants and Private Placement Warrants" of our audited financial statements for further information.

Interest income

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
Interest income	$ (178,109)	$ (258,375)	$ (146,425)	$ 80,266	$ (111,950)

Interest income decreased by $80.3 million to $178.1 million for the year ended March 31, 2026, compared to $258.4 million for the year ended March 31, 2025. This decrease is primarily due to lower cash equivalents and marketable securities balances in our interest-bearing accounts as well as lower interest rates.

Interest income increased by $112.0 million to $258.4 million for the year ended March 31, 2025, compared to $146.4 million for the year ended March 31, 2024. This increase is primarily due to higher cash balances in our interest-bearing cash accounts.

Income tax expense

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
Income tax expense	$ 133,329	$ 48,174	$ 21,503	$ 85,155	$ 26,671

Income tax expense increased by $85.2 million to $133.3 million for the year ended March 31, 2026, compared to $48.2 million for the year ended March 31, 2025. The increase was primarily due to income associated with the gain on litigation settlement. Refer to Note 5, "Recent Transactions and Developments" of our audited financial statements for additional information.

Income tax expense increased by $26.7 million to $48.2 million for the year ended March 31, 2025, compared to $21.5 million for the year ended March 31, 2024. The increase was primarily due to our fluctuating earnings by legal entity in various jurisdictions over the periods. As disclosed, the tax expense for the year ended March 31, 2024 was impacted by the 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.

Income (loss) from discontinued operations, net of tax

	Years Ended March 31,			Change	
	2026	2025	2024	2026 vs. 2025	2025 vs. 2024
			(in thousands)		
Income (loss) from discontinued operations, net of tax	$ —	$ 373,030	$ (315,147)	$ (373,030)	$ 688,177

Income from discontinued operations, net of tax was $373.0 million for the year ended March 31, 2025 and reflects the gain on sale of subsidiary interests resulting from the sale of our entire equity interest in our majority-owned subsidiary, Dermavant, to Organon in October 2024, partially offset by Dermavant's net losses. Loss from discontinued operations, net of tax was $315.1 million for the year ended March 31, 2024 and represents the financial results of Dermavant. Refer to Note 6, "Discontinued Operations" of our audited financial statements for additional information.

Liquidity and Capital Resources

For the years ended March 31, 2026, 2025 and 2024, we had net losses from continuing operations of $397.9 million and $729.8 million and had net income from continuing operations of approximately $4.5 billion, respectively. As of March 31, 2026, we had cash, cash equivalents and marketable securities of approximately $4.3 billion and our accumulated deficit was $501.8 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 I, Item 1A. of this Annual Report on Form 10-K. 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 March 31, 2026 included obligations under our leases (see Note 11, "Leases" of our audited financial statements). As of March 31, 2026, our subsidiary, Immunovant, had an accumulated accrual of $42.5 million of non-cancelable contractual costs as a result of the discontinuation of batoclimab, of which $39.0 million was recognized as research and development expense during the year ended March 31, 2026. Beyond this, we do not currently have any other material contractually obligated minimum purchases or firm non-cancelable purchase commitments. We anticipate other purchases in the ordinary course of business and have other payment obligations as discussed below.

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.

Potential material future milestone and royalty payments as of March 31, 2026 pursuant to certain key asset acquisition and license agreements are as follows:

- ***Anti-FcRn franchise (Immunovant)***: up to a maximum of $420.0 million to HanAll upon the achievement of certain regulatory and sales milestone events and tiered mid-single-digits to mid-teens royalty on net sales.

- ***Brepocitinib (Priovant)***: mid tens-of-millions sales milestone payment to Pfizer if aggregate net sales in a given year exceed a mid-hundreds-of-millions amount and tiered sub-teens royalty on net sales.

- ***Mosliciguat (Pulmovant):*** up to a maximum of $280.0 million to Bayer upon the achievement of certain development, regulatory and commercial milestone events and tiered high-single-digits royalty on net sales.

- ***LNP Technology (Genevant):*** up to 20% of Royalty-Related Receipts (as defined in the Cross-License Agreement).

We have further commitments not reflected above relating to other asset acquisition and license agreements entered and 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.

Additionally, 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 has authorized various share repurchase programs, including a $1.5 billion (excluding fees and expenses) program that was completed in June 2025 and a subsequent program authorized in June 2025 and subsequently increased in March 2026, allowing for aggregate repurchases up to $1.0 billion (excluding fees and expenses). As of March 31, 2026, approximately $890.3 million remains available for share repurchases. During the year ended March 31, 2026, we repurchased 24,225,812 shares (including 270,000 common shares with a trade date of March 31, 2025 that settled on April 1, 2025) for an aggregate purchase price of approximately $318.1 million (including fees and expenses). During the year ended March 31, 2025, we repurchased 128,361,786 shares for an aggregate purchase price of approximately $1.3 billion (including fees and expenses), including 71,251,083 shares repurchased from Sumitomo Pharma Co., Ltd. at $9.10 per share for approximately $648.4 million.

Our operations to date have been financed primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements, including the following completed during the years ended March 31, 2026, 2025 and 2024:

RSL Equity Financing Transaction

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

Consolidated Vant Equity Financing Transactions

Immunovant

In October 2023, Immunovant completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by us on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of $38.00 per share. Concurrent with the public offering, we purchased 4,473,684 shares of Immunovant's common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of $38.00 per share. The net proceeds to Immunovant were approximately $466.7 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses.

In January 2025, Immunovant entered into a share purchase agreement pursuant to which Immunovant issued 22,500,000 shares of its common stock (including 16,845,010 shares of common stock purchased by us) at a price of $20.00 per share in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the "IMVT PIPE"). The gross proceeds to Immunovant in the IMVT PIPE were approximately $450.0 million, of which $336.9 million related to our participation.

In December 2025, Immunovant completed an underwritten offering of 26,200,000 shares of its common stock (including 16,666,666 shares of common stock purchased by us) at a price of $21.00 per share, for net proceeds to Immunovant of approximately $543.6 million after deducting underwriting discounts and offering expenses.

Sale of Subsidiary Interests

Dermavant

On October 28, 2024, we completed the sale of our entire equity interest in our majority-owned subsidiary, Dermavant, to Organon.

Pursuant to the Merger Agreement, Organon agreed to acquire Dermavant for aggregate cash consideration comprising (i) a payment of $175.0 million payable at the closing of the Dermavant Transaction, subject to certain adjustments, (ii) a $75.0 million milestone payment payable upon FDA approval of VTAMA (the "Product") for the treatment of atopic dermatitis (the "AD Approval Milestone") and (iii) up to $950.0 million in additional milestone payments payable upon achievement of certain tiered net sales amounts (each less than or equal to $1.0 billion) with respect to the Product. Additionally, Organon agreed to make tiered royalty payments of (x) low-to-mid single digit percentages with respect to annual net sales of the Product up to $1.0 billion and (y) 30% with respect to annual net sales of the Product above $1.0 billion. Such consideration and royalty payments are subject to certain post-closing adjustments and are payable to all of Dermavant's equity holders, including holders of Dermavant restricted stock units, options and warrants, on a pro rata basis relative to their ownership of Dermavant prior to the closing of the Dermavant Transaction (in each case, after giving effect to the liquidation preference of Dermavant's preference shares, all of which are held by us, and otherwise in accordance with the applicable terms of such securities). Under the liquidation preference of Dermavant's preference shares, we are entitled to receive 100% of the first $270.0 million of consideration paid pursuant to the Merger Agreement. We received $183.6 million in cash in October 2024 upon the closing of the Dermavant Transaction, subject to certain post-closing adjustments that are not expected to be significant. The AD Approval Milestone was achieved in December 2024, and the Company received payment of the $75.0 million AD Approval Milestone in January 2025, pursuant to the terms of the Merger Agreement.

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

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

Proteovant

In August 2023, we completed a transaction with SK Biopharmaceuticals Co., Ltd. ("SK Bio"), a subsidiary of SK, Inc., pursuant to which SK Bio purchased all of our shares in Proteovant in exchange for $47.5 million.

Telavant

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

Pursuant to the Stock Purchase Agreement, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately $7.1 billion in cash at the closing of the Roche Transaction in December 2023, as well as a one-time milestone payment of $150 million in cash, paid in August 2024 following the initiation of a Phase 3 trial in UC. The $7.1 billion in closing consideration and $150 million one-time milestone payment were paid to all of Telavant's equity holders, including holders of Telavant restricted stock units, on a pro rata basis relative to their ownership of Telavant prior to the closing of the Roche Transaction. We received an upfront payment of approximately $5.2 billion in cash as our pro rata portion of the consideration upon closing of the Roche Transaction and a one-time milestone payment of approximately $110.4 million as our pro rata portion of the milestone payment following initiation of a Phase 3 trial in UC.

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 current 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 through 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." in Part I, Item 1A. of this Annual Report for more information.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended March 31, 2026, 2025 and 2024:

	Years Ended March 31,		
	2026	**2025**	**2024**
		(in thousands)	
Net cash used in operating activities	$ (750,349)	$ (839,451)	$ (765,268)
Net cash (used in) provided by investing activities	$ (682,333)	$ (1,766,291)	$ 5,203,623
Net cash provided by (used in) financing activities	$ 134,236	$ (1,219,794)	$ 419,364

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 year ended March 31, 2026, cash used in operating activities decreased by $89.1 million to $750.3 million compared to $839.5 million for the year ended March 31, 2025. This decrease was primarily due to certain cost savings during the year ended March 31, 2026 as a result of the sale of Dermavant along with lower cash compensation during the year ended March 31, 2026 as a result of higher one-time cash awards made pursuant to the Senior Executive Compensation Program during the year ended March 31, 2025. These decreases were partially offset by lower cash receipts from revenues in part as a result of the sale of Dermavant, less interest income received and greater cash requirements to advance our existing research and development programs, including the anti-FcRn franchise and brepocitinib, during the year ended March 31, 2026.

For the year ended March 31, 2025, cash used in operating activities increased by $74.2 million to $839.5 million compared to $765.3 million for the year ended March 31, 2024, largely reflecting greater cash requirements to advance our research and development programs during the year ended March 31, 2025.

Investing Activities

For the year ended March 31, 2026, cash used in investing activities decreased by approximately $1.1 billion to $682.3 million compared to $1.8 billion for the year ended March 31, 2025. The decrease was primarily driven by increased proceeds from sales and maturities of marketable securities, partially offset by increased purchases of marketable securities during the year ended March 31, 2026.

For the year ended March 31, 2025, cash flow from investing activities changed by approximately $7.0 billion to net cash used in investing activities of approximately $1.8 billion for the year ended March 31, 2025 from net cash provided by investing activities of $5.2 billion for the year ended March 31, 2024. This change in cash flow was primarily due to purchases of marketable securities, partially offset by maturities, during the year ended March 31, 2025 and the proceeds received upon closing of the Roche Transaction during the year ended March 31, 2024.

Financing Activities

For the year ended March 31, 2026, cash flow from financing activities changed by approximately $1.4 billion to net cash provided by financing activities of $134.2 million for the year ended March 31, 2026 compared to net cash used in financing activities of $1.2 billion for the year ended March 31, 2025. This change was primarily due to a decrease in cash used for the repurchase of our common shares, an increase in cash proceeds from exercise of stock options and an increase in cash proceeds from the issuance of subsidiary common shares, net of issuance costs paid, during the year ended March 31, 2026.

For the year ended March 31, 2025, cash flow from financing activities changed by approximately $1.6 billion to net cash used in financing activities of $1.2 billion for the year ended March 31, 2025 from net cash provided by financing activities of $419.4 million for the year ended March 31, 2024. During the year ended March 31, 2025, net cash used in financing activities was primarily driven by the repurchase of approximately $1.3 billion of our common shares, partially offset by the issuance of common shares of our majority-owned subsidiary Immunovant. During the year ended March 31, 2024, net proceeds were primarily generated by the issuance of common shares of our majority-owned subsidiary Immunovant as well as the issuance of our common shares pursuant to purchase and sale agreements entered into with certain institutional investors.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingencies as of the dates of the 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.

While our significant accounting policies are described in more detail in Note 2, "Summary of Significant Accounting Policies" in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses, Including Clinical Trial Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. We record accruals for estimated costs of research and development activities, including preclinical studies, clinical trials and contract manufacturing, conducted by third-party service providers. Our process for determining such estimates includes reviewing open contracts, vendor agreements and purchase orders; communicating with our internal personnel and external service providers to understand the progress or stage of completion of services performed on our behalf; and estimating the associated costs for these services when we have not yet been invoiced. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

We recognize expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract. This may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on various factors, including the successful enrollment of patients and the completion of clinical trial milestones. The majority of our service providers invoice us in arrears based on a pre-determined schedule or when contractual milestones are met. In making these estimates, we consider various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment. If the actual timing of the performance of services or the level of effort varies from our estimate, the accrual or prepaid expense is adjusted accordingly.

Other examples of estimated accrued research and development expenses include fees paid to:

a. investigative sites in connection with clinical trials;
b. vendors in connection with preclinical and clinical development activities; and
c. CMOs in connection with the production of product and clinical trial materials.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period.

Valuation of Investment in Datavant

We hold an equity method investment in Datavant, which is a privately-held company. We do not consolidate Datavant as we do not have a controlling financial interest. Our investment in Datavant is subject to the equity method of accounting, and we have elected the fair value option to continuously remeasure the investment to fair value each reporting period with changes in fair value reflected in earnings. We have engaged an independent valuation specialist to determine the fair value as of each reporting date.

The fair value of our investment in Datavant uses significant unobservable inputs and is therefore classified as a Level 3 financial instrument. The estimate of fair value for this investment was determined using the income approach, market approach and implementation of the option pricing method ("OPM"). The income approach is based on the future expected cash flows, which are derived from certain assumptions attributable to Datavant including estimates of revenue growth rate, earnings before interest, taxes, depreciation and amortization and terminal growth rate. These expected cash flows are then discounted to their present value using a discount rate that reflects the risk and time value of money. The market approach estimates value by using valuation multiples derived from the stock prices of comparable publicly traded companies to determine the company's equity value. 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.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which requires 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 our fiscal year beginning April 1, 2025, with early adoption permitted. The amendments should be applied prospectively, however retrospective application is permitted. We adopted this ASU prospectively for the fiscal year ended March 31, 2026. This resulted in expanded disclosures in line with the requirements of the ASU.

In September 2025, the FASB issued ASU 2025-07, "Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract", which refines the scope of the guidance on derivatives in ASC 815 and clarifies the guidance on share-based payments from a customer in ASC 606. This guidance is effective for fiscal years and interim periods beginning after December 15, 2026, with early adoption permitted. These requirements may be applied prospectively or on a modified retrospective basis through a cumulative-effect adjustment to the opening balance of retained earnings. We early adopted this guidance during the quarter ended March 31, 2026. We applied the derivative scope refinements guidance on a modified retrospective basis and applied the share-based payments guidance on a prospective basis. The adoption of this guidance had no impact on our consolidated financial statements.

ITEM 7A. 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, foreign currency sensitivities and equity price risk.

Interest Rate Sensitivity

As of March 31, 2026, we had cash, cash equivalents and marketable securities of approximately $4.3 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 the in-licensing of product candidates. 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 average 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 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 consolidated financial statements.

Equity Price Risk

As of March 31, 2026, 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 March 31, 2026 by approximately $40.8 million.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Roivant Sciences Ltd.
Index

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID No. 42)	155
Consolidated Financial Statements	
Consolidated Balance Sheets as of March 31, 2026 and 2025	158
Consolidated Statements of Operations for the Years Ended March 31, 2026, 2025 and 2024	159
Consolidated Statements of Comprehensive (Loss) Income for the Years Ended March 31, 2026, 2025 and 2024	160
Consolidated Statements of Shareholders' Equity for the Years Ended March 31, 2026, 2025 and 2024	161
Consolidated Statements of Cash Flows for the Years Ended March 31, 2026, 2025 and 2024	164
Notes to Consolidated Financial Statements	166

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Roivant Sciences Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Roivant Sciences Ltd. (the Company) as of March 31, 2026 and 2025, the related consolidated statements of operations, comprehensive (loss) income, shareholders' equity and cash flows for each of the three years in the period ended March 31, 2026, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2026 and 2025, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2026, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of March 31, 2026, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated May 20, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Clinical Trial Accrual

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by contract research organizations. In making these estimates, the Company considers various factors, including status and timing of services performed, the number of patients enrolled and the rate of patient enrollment.

Auditing the Company's accrual for certain clinical trial costs requires a greater extent of audit effort due to the fact that information necessary to estimate the accruals is accumulated from clinical research organizations and the Company's assessment of that information is subject to variability and uncertainty. In addition, in certain circumstances, the determination of the nature and amount of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that addressed the identified risks related to the information used in the Company's process for recording clinical trial accruals. For example, we tested controls over management's review of clinical trial progress in comparison to information and invoices received from third parties, and over the completeness and accuracy of data used to calculate the accrual.

To test the clinical trial accrual, our audit procedures included, among others, reading a sample of the Company's agreements with the service providers to understand key financial and contractual terms and testing the accuracy and completeness of the underlying data used in the accrual computations. We also evaluated management's estimates of the vendor's progress for a sample of clinical trials by making direct inquiries of the Company's operations personnel overseeing the clinical trials and obtaining information directly from certain service providers about the service providers' estimate of costs that had been incurred through March 31, 2026. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

Valuation of Investment in Datavant

Description of the Matter

At March 31, 2026, the fair value of the Company's minority equity investment in Heracles Parent, L.L.C. ("Datavant") was $233.2 million and was classified as Level 3 within the fair value hierarchy. As discussed in Notes 4 and 14 to the consolidated financial statements, the Company has elected the fair value option to account for its investment in Datavant. Management determines the fair value of the Company's investment in Datavant using the income approach, market approach, and implementation of the option pricing method, which uses significant unobservable inputs. Determining the fair value of the Company's investment in Datavant requires management to make significant judgments about the valuation methodologies, including the unobservable inputs and other assumptions and estimates used in the measurements.

Auditing the fair value of the Company's investment in Datavant is especially complex and requires substantial auditor judgment due to the significant estimation required in determining the fair value of the investment in Datavant. In particular, to value its investment in Datavant, the Company used significant unobservable inputs such as the discount rate, revenue growth rate, earnings before interest, taxes, depreciation and amortization and terminal growth rate, which are affected by expectations about future market or economic conditions.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the process for valuing the Company's investment in Datavant, including controls over management's review of the significant inputs described above. To test the fair value of the Company's investment in Datavant, our audit procedures included, among others, assessing the valuation methodologies used and testing the significant unobservable inputs discussed above, including testing the completeness, accuracy and relevance of underlying data used by the Company in the valuation. We compared the significant inputs and underlying data used by management to current industry and economic trends, historical financial results, and other relevant factors. We analyzed the significant unobservable inputs to evaluate the change in the fair value of the Company's investment in Datavant resulting from changes in the inputs. We also assessed the historical accuracy of the underlying financial projections developed by Datavant by comparing to actual historical results. In addition, we involved our valuation specialists to assist in evaluating the valuation methodology and significant unobservable inputs described above used to develop the fair value estimate. The valuation specialists' procedures included independently developing fair value estimates and comparing them to the amounts recorded.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2016.

Iselin, New Jersey
May 20, 2026

ROIVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2026	March 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 1,419,232	$ 2,715,411
Marketable securities (held at fair value as of March 31, 2026)	2,872,601	2,171,480
Litigation settlement receivable	770,235	—
Other current assets	105,316	113,173
Total current assets	5,167,384	5,000,064
Property and equipment, net	11,986	12,056
Operating lease right-of-use assets	80,416	89,021
Investments measured at fair value	407,985	302,939
Other assets	40,916	32,860
Total assets	$ 5,708,687	$ 5,436,940
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 18,002	$ 23,691
Accrued expenses	205,823	114,294
Operating lease liabilities	11,147	9,842
Income tax payable	45,689	416
Other current liabilities	583	1,168
Total current liabilities	281,244	149,411
Liability instruments measured at fair value	—	9,981
Operating lease liabilities, noncurrent	96,291	90,328
Income tax payable, noncurrent	38,670	—
Other liabilities	70	22
Total liabilities	416,275	249,742
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Common shares, par value $0.0000000341740141 per share, 7,000,000,000 shares authorized and 720,352,386 and 695,938,323 shares issued and outstanding at March 31, 2026 and 2025, respectively	—	—
Additional paid-in capital	5,024,826	4,562,107
(Accumulated deficit) / retained earnings	(501,814)	116,060
Accumulated other comprehensive income	4,358	9,438
Shareholders' equity attributable to Roivant Sciences Ltd.	4,527,370	4,687,605
Noncontrolling interests	765,042	499,593
Total shareholders' equity	5,292,412	5,187,198
Total liabilities and shareholders' equity	$ 5,708,687	$ 5,436,940

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

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

	Years Ended March 31,		
	2026	2025	2024
Revenue	$ 8,260	$ 29,053	$ 32,713
Operating expenses:			
Cost of revenues	1,285	911	1,599
Research and development (includes $47,867, $39,780 and $32,400 of share-based compensation expense for the years ended March 31, 2026, 2025 and 2024, respectively)	681,812	550,413	439,909
Acquired in-process research and development	—	—	26,450
General and administrative (includes $298,298, $239,505 and $154,873 of share-based compensation expense for the years ended March 31, 2026, 2025 and 2024, respectively)	610,466	591,410	416,133
Total operating expenses	1,293,563	1,142,734	884,091
Gain on sale of Telavant net assets	—	110,387	5,348,410
Gain on litigation settlement	770,235	—	—
(Loss) income from operations	(515,068)	(1,003,294)	4,497,032
Change in fair value of investments	(105,046)	(55,186)	47,973
Change in fair value of liability instruments	47,704	(15,756)	46,838
Gain on deconsolidation of subsidiaries	(11,027)	(3,108)	(32,772)
Interest income	(178,109)	(258,375)	(146,425)
Other (income) expense, net	(4,012)	10,721	13,562
(Loss) income from continuing operations before income taxes	(264,578)	(681,590)	4,567,856
Income tax expense	133,329	48,174	21,503
(Loss) income from continuing operations, net of tax	(397,907)	(729,764)	4,546,353
Income (loss) from discontinued operations, net of tax	—	373,030	(315,147)
Net (loss) income	(397,907)	(356,734)	4,231,206
Net loss attributable to noncontrolling interests	(98,136)	(184,753)	(117,720)
Net (loss) income attributable to Roivant Sciences Ltd.	$ (299,771)	$ (171,981)	$ 4,348,926
Amounts attributable to Roivant Sciences Ltd.:			
(Loss) income from continuing operations, net of tax	$ (299,771)	$ (545,166)	$ 4,662,703
Income (loss) from discontinued operations, net of tax	—	373,185	(313,777)
Net (loss) income attributable to Roivant Sciences Ltd.	$ (299,771)	$ (171,981)	$ 4,348,926
Net (loss) income per common share, basic:			
(Loss) income from continuing operations, net of tax	$ (0.43)	$ (0.75)	$ 5.95
Income (loss) from discontinued operations, net of tax	$ —	$ 0.51	$ (0.40)
Net (loss) income	$ (0.43)	$ (0.24)	$ 5.55
Net (loss) income per common share, diluted:			
(Loss) income from continuing operations, net of tax	$ (0.54)	$ (0.75)	$ 5.61
Income (loss) from discontinued operations, net of tax	$ —	$ 0.51	$ (0.38)
Net (loss) income	$ (0.54)	$ (0.24)	$ 5.23
Weighted average shares outstanding:			
Basic	693,864,530	725,395,624	783,248,906
Diluted	693,864,530	725,395,624	831,049,444

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

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

	Years Ended March 31,		
	2026	2025	2024
Net (loss) income	$ (397,907)	$ (356,734)	$ 4,231,206
Other comprehensive (loss) income:			
Change in fair value of debt due to change in subsidiary credit risk	—	(1,200)	—
Unrealized losses on available-for-sale securities	(2,579)	—	—
Foreign currency translation adjustment	(3,027)	(5,210)	(936)
Amounts reclassified from accumulated other comprehensive (loss) income	(976)	19,869	—
Total other comprehensive (loss) income	(6,582)	13,459	(936)
Comprehensive (loss) income	(404,489)	(343,275)	4,230,270
Comprehensive loss attributable to noncontrolling interests	(99,638)	(184,815)	(117,190)
Comprehensive (loss) income attributable to Roivant Sciences Ltd.	$ (304,851)	$ (158,460)	$ 4,347,460

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

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

	Shareholders' Equity						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	(Accumulated Deficit) / Retained Earnings	Noncontrolling Interests	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2023	760,143,393	$ —	$ 4,933,137	$ (2,617)	$ (3,772,754)	$ 449,821	$ 1,607,587
Issuance of the Company's common shares, net of issuance costs	19,600,685	—	199,822	—	—	—	199,822
Issuance of the Company's common shares in connection with equity incentive plans, net of forfeitures, and tax withholding payments	18,926,077	—	10,857	—	—	—	10,857
Issuance of the Company's common shares related to settlement of warrants	7,554,549	—	83,264	—	—	—	83,264
Issuance of the Company's common shares related to settlement of transaction consideration	313,023	—	—	—	—	—	—
Issuance of the Company's common shares under employee stock purchase plan	140,227	—	951	—	—	—	951
Issuance of subsidiary common shares, net of issuance costs	—	—	129,763	—	—	108,970	238,733
Exercise and vesting of subsidiary share awards	—	—	3,192	—	—	2,550	5,742
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	(106,531)	—	—	106,531	—
Deconsolidation of subsidiaries	—	—	—	—	—	(35,148)	(35,148)
Dividend declared by subsidiary	—	—	—	—	—	(6,000)	(6,000)
Disposition of Telavant	—	—	—	—	—	(87,500)	(87,500)
Share-based compensation	—	—	142,037	—	—	57,914	199,951
Foreign currency translation adjustment	—	—	—	(1,466)	—	530	(936)
Net income (loss)	—	—	—	—	4,348,926	(117,720)	4,231,206
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, net of forfeitures, and tax withholding payments	17,503,515	—	7,354	—	—	—	7,354
Issuance of subsidiary common shares, net	—	—	77,267	—	—	47,162	124,429
Sale of interests in subsidiary	—	—	—	—	—	(48,079)	(48,079)
Exercise and vesting of subsidiary share awards	—	—	2,852	—	—	2,175	5,027
Issuance of the Company's common shares under employee stock purchase plan	118,640	—	1,028	—	—	—	1,028
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	(142,100)	—	—	142,100	—
Deconsolidation of subsidiary	—	—	—	—	—	(3,706)	(3,706)
Repurchase of the Company's common shares	(128,361,786)	—	(1,005,101)	—	(288,131)	—	(1,293,232)
Share-based compensation	—	—	224,315	—	—	64,808	289,123
Change in fair value of debt due to change in subsidiary credit risk	—	—	—	(1,200)	—	—	(1,200)
Foreign currency translation adjustment	—	—	—	(5,148)	—	(62)	(5,210)
Amounts reclassified from accumulated other comprehensive (loss) income	—	—	—	19,869	—	—	19,869
Net loss	—	—	—	—	(171,981)	(184,753)	(356,734)
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	48,518,151	—	136,891	—	—	—	136,891
Vesting of Earn-Out Shares	—	—	57,685	—	—	—	57,685
Issuance of subsidiary common shares, net of issuance costs	—	—	108,902	—	—	84,703	193,605
Contribution from minority interest holder to subsidiary	—	—	—	—	—	39,250	39,250
Exercise and vesting of subsidiary share awards	—	—	26,998	—	—	27,457	54,455
Issuance of subsidiary common shares to the Company and cash contributions to majority-owned subsidiaries	—	—	(162,659)	—	—	162,659	—

Repurchase of subsidiary common shares	—	—	(1,318)	—	—	(82)	(1,400)
Repurchase of the Company's common shares	(24,225,812)	—	—	—	(318,103)	—	(318,103)
Issuance of the Company's common shares under employee stock purchase plan	121,724	—	1,155	—	—	—	1,155
Share-based compensation	—	—	295,065	—	—	51,100	346,165
Amounts reclassified from accumulated other comprehensive (loss) income	—	—	—	(976)	—	—	(976)
Unrealized losses on available-for-sale securities	—	—	—	(2,579)	—	—	(2,579)
Foreign currency translation adjustment	—	—	—	(1,525)	—	(1,502)	(3,027)
Net loss	—	—	—	—	(299,771)	(98,136)	(397,907)
Balance at March 31, 2026	**720,352,386**	**$ —**	**$ 5,024,826**	**$ 4,358**	**$ (501,814)**	**$ 765,042**	**$ 5,292,412**

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

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

	Years Ended March 31,		
	2026	2025	2024
Cash flows from operating activities:			
Net (loss) income	$ (397,907)	$ (356,734)	$ 4,231,206
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Share-based compensation	346,165	289,029	199,627
Change in fair value of investments	(105,046)	(55,186)	47,973
Change in fair value of debt and liability instruments	47,704	(113,078)	78,943
Gain on sale of subsidiary interests	—	(376,506)	—
Gain on deconsolidation of subsidiaries	(11,027)	(3,108)	(32,772)
Gain on sale of Telavant net assets	—	(110,387)	(5,348,410)
Impairment loss on operating lease right-of-use assets	15,594	—	—
Accretion of discount and amortization of premium on available-for-sale marketable securities, net	(22,992)	—	—
Accretion of discount and amortization of premium on held-to-maturity marketable securities, net	(13,520)	(69,959)	—
Realized gain from sales of marketable securities	(976)	—	—
Loss on extinguishment of debt	—	8,848	—
Depreciation and amortization	3,348	14,071	22,036
Non-cash lease expense	8,276	6,843	6,845
Other	1,828	3,762	10,249
Changes in assets and liabilities, net of effects from acquisition and divestiture:			
Other current assets	11,459	(25,070)	(81,478)
Other assets	(7,416)	(8,758)	16,488
Litigation settlement receivable	(770,235)	—	—
Accounts payable	3,418	(18,168)	22,684
Accrued expenses	59,326	(10,070)	40,150
Operating lease liabilities	(2,385)	(5,700)	(8,326)
Accrued interest	—	—	21,977
Income tax payable	85,045	(10,053)	9,927
Other liabilities	(1,008)	773	(2,387)
Net cash used in operating activities	(750,349)	(839,451)	(765,268)
Cash flows from investing activities:			
Marketable securities, available-for-sale			
Purchases	(4,795,855)	—	—
Proceeds from maturities	1,122,300	—	—
Proceeds from sales	821,367	—	—
Marketable securities, held-to-maturity			
Purchases	—	(4,061,521)	—
Proceeds from maturities	2,185,000	1,960,000	—
Proceeds from sale of Telavant net assets, net	—	110,387	5,233,396
Proceeds from sale of subsidiary interests	—	260,586	47,500

Cash decrease upon deconsolidation of subsidiaries	(4,418)	(31,223)	(84,483)
Purchase of property and equipment	(8,209)	(4,599)	(1,382)
Other	(2,518)	79	8,592
Net cash (used in) provided by investing activities	(682,333)	(1,766,291)	5,203,623
Cash flows from financing activities:			
Repurchase of the Company's common shares	(318,103)	(1,293,232)	—
Repurchase of subsidiary common shares	(1,400)	—	—
Proceeds from issuance of the Company's common shares, net of issuance costs paid	—	—	199,822
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	193,605	112,782	238,733
Repayment of debt by subsidiary	—	(51,979)	(29,158)
Contribution from minority interest holder to subsidiary	39,250	—	—
Proceeds from exercise of the Company's and subsidiary stock options	268,350	49,597	54,314
Taxes paid related to net settlement of equity awards	(48,621)	(37,216)	(37,715)
Proceeds from issuance of the Company's common shares under employee stock purchase plan	1,155	1,028	951
Payments on principal portion of finance lease obligations	—	(774)	(1,547)
Payment of subsidiary dividend	—	—	(6,000)
Proceeds from exercise of the Company's warrants	—	—	5
Payment for redemptions of the Company's warrants	—	—	(41)
Net cash provided by (used in) financing activities	134,236	(1,219,794)	419,364
Effect of exchange rate changes on cash, cash equivalents and restricted cash	3,767	747	616
Net change in cash, cash equivalents and restricted cash	(1,294,679)	(3,824,789)	4,858,335
Cash, cash equivalents and restricted cash at beginning of period	2,725,661	6,550,450	1,692,115
Cash, cash equivalents and restricted cash at end of period	$ 1,430,982	$ 2,725,661	$ 6,550,450
Non-cash investing and financing activities:			
Cashless exercise of the Company's warrants	$ —	$ —	$ 83,258
Issuance of subsidiary shares in connection with debt renegotiation	$ —	$ 11,647	$ —
Operating lease right-of-use assets obtained and exchanged for operating lease liabilities	$ 9,605	$ 51,364	$ 1,790
Reclassification of earn-out shares liability to additional paid-in capital upon vesting	$ 57,685	$ —	$ —
Taxes payable related to net settlement of equity awards	$ 31,114	$ —	$ —
Other	$ 3,352	$ 59	$ 441
Supplemental disclosure of cash paid:			
Interest paid	$ —	$ 5,963	$ 10,268

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

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 March 31, 2026, the Company had cash, cash equivalents and marketable securities of approximately $4.3 billion and its accumulated deficit was $501.8 million. For the years ended March 31, 2026, 2025 and 2024, the Company had net losses from continuing operations of $397.9 million and $729.8 million and net income from continuing operations of approximately $4.5 billion, 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 audited consolidated financial statements and notes thereto have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

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 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. Certain prior year amounts have been reclassified to conform with the current period presentation. These reclassifications had no effect on the previously reported results of operations. 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 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 consolidated balance sheets.

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

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 consolidated balance sheets as of March 31, 2026 or 2025. The Company classified the results of Dermavant as discontinued operations in its consolidated statements of operations for the years ended March 31, 2025 and 2024. The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. The discussions in these notes to the consolidated financial statements relate solely to the Company's continuing operations, unless otherwise noted. For further discussion of 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 credit risk concentrations 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 March 31, 2026 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 16, "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.

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

	March 31, 2026	March 31, 2025
Cash and cash equivalents	$ 1,419,232	$ 2,715,411
Restricted cash (included in "Other current assets")	3,858	2,358
Restricted cash (included in "Other assets")	7,892	7,892
Cash, cash equivalents and restricted cash	$ 1,430,982	$ 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, including those that have maturity dates beyond one year from the balance sheet date, are included in current assets on the consolidated balance sheets due to their availability for use in current operations. As of March 31, 2026, marketable securities, consisting of amounts invested in United States ("U.S.") Treasury securities and corporate bonds, are classified as available-for-sale and carried at fair value. Unrealized holding gains and losses, net of income taxes, on available-for-sale debt securities are reported as a separate component of accumulated other comprehensive (loss) income in stockholders' equity until realized. The cost of available-for-sale securities sold and the amount reclassified out of accumulated other comprehensive (loss) income into earnings is determined using the specific identification method. As of March 31, 2025, the Company's marketable securities were classified as held-to-maturity and carried at amortized cost. Interest income is recorded as earned within "Interest income" in the 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) Property and Equipment

Property and equipment, consisting primarily of computers, laboratory and other equipment, furniture and fixtures, software and leasehold improvements, is recorded at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation of property and equipment is recorded using the straight-line method over the estimated useful lives of the related assets once the asset has been placed in service. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter. The following table provides the range of estimated useful lives used for each asset type:

Property and Equipment	Estimated Useful Life
Computers	3 years
Laboratory and other equipment	5 - 10 years
Furniture and fixtures	7 years
Software	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. Recoverability is measured by comparison of the book values of the assets to the future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

(I) Investments in Equity Securities

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 these investments. See Note 4, "Equity Method Investments."

(J) 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 share liabilities (prior to vesting during the quarter ended December 31, 2025) issued in connection with the Company's business combination (the "Business Combination") with Montes Archimedes Acquisition Corp. ("MAAC") (as discussed in Note 13, "Earn-Out Shares, Public Warrants and Private Placement Warrants"); cash; cash equivalents, consisting of money market funds; marketable securities, consisting of U.S. Treasury securities and corporate bonds; receivables; and accounts payable.

The shares of Arbutus common stock 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, receivables 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 included in Level 2 of the fair value hierarchy, are classified as available-for-sale or held-to-maturity (prior to December 31, 2025) and are carried at fair value or amortized cost, respectively.

(K) Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. R&D expenses primarily consist of costs associated with preclinical studies and clinical trials as well as employee-related expenses, such as salaries, share-based compensation and benefits, for employees engaged in R&D activities. The Company records accruals for estimated costs of R&D activities, including preclinical studies, clinical trials and contract manufacturing, conducted by third-party service providers. The Company determines the estimates by reviewing open contracts, vendor agreements and purchase orders; communicating with internal personnel and external service providers to understand the progress or stage of completion of services performed on its behalf; and estimating the associated costs for these services that have not yet been invoiced. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual or prepaid expense is adjusted accordingly.

(L) 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.

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

(M) 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 the Company's 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. Additionally, G&A expenses include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates.

(N) Leases

The Company determines if an arrangement includes a lease at the inception of the agreement. Leases are classified at lease commencement as either operating leases or finance leases. Operating leases are included in "Operating lease right-of-use assets," "Operating lease liabilities" and "Operating lease liabilities, noncurrent" on the accompanying consolidated balance sheets. Commitments under finance leases are not significant and are included in "Property and equipment, net," and "Other current liabilities" on the accompanying consolidated balance sheets. For each of the Company's lease arrangements, the Company records a right-of-use asset representing the Company's right to use an underlying asset for the lease term and a lease liability representing the Company's obligation to make lease payments. Lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the expected lease term. If the interest rate implicit in the Company's leases is not readily determinable, in determining the weighted-average discount rate used to calculate the net present value of lease payments, the Company utilizes an estimate of its incremental borrowing rate. The Company's incremental borrowing rates are determined based on the term of the lease, the economic environment of the lease, and the effect of collateralization. Lease expense for the Company's leases is recognized on a straight-line basis over the lease term and variable lease costs are expensed as incurred.

The Company elected the practical expedient not to apply the recognition and measurement requirements to short-term leases, which are any leases with a term of one year or less as of the lease commencement date. Leases may require the Company to pay additional amounts for taxes, insurance, maintenance and other expenses, which are generally referred to as non-lease components. The Company has elected the practical expedient to combine lease and non-lease components. If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of relevant factors present as of the lease commencement date.

(O) Income Taxes

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 it is more likely than not that deferred tax assets will not be realized. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company's policy is to recognize interest and/or penalties related to income tax matters in provision for income taxes.

(P) Share-Based Compensation

Share-based awards to employees, directors and consultants, including stock options, restricted stock units ("RSUs"), performance options, performance restricted stock units ("PSUs") and capped value appreciation rights ("CVARs"), are measured at fair value on the date of the grant and that fair value is recognized as share-based compensation expense in the Company's consolidated statements of operations over the requisite service period of the respective award. The estimated fair value of awards that contain performance conditions is expensed when the Company concludes that it is probable that the performance condition will be achieved. The Company may grant awards with graded-vesting features. When such awards have only service vesting requirements, the Company elected to record share-based compensation expense on a straight-line basis. If awards with graded-vesting features contain performance or market conditions, then the Company records share-based compensation expense using the accelerated attribution method.

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. For performance-based awards with market conditions, the Company determines the fair value of the awards as of the grant date using a Monte Carlo simulation model. When determining the grant-date fair value of stock-based awards, management further considers whether an adjustment is required to the observable market price or volatility of the Company's common stock that is used in the valuation as a result of material non-public information, if that information is expected to result in a material increase in share price.

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. As of March 31, 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. One of the inputs to the Black-Scholes option pricing model is the fair value of the Company's common shares. 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.

The Company applies similar methodology to measure the fair value of share-based awards issued by its Vants. Certain assumptions vary based on circumstances specific to each Vant. 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.

Stock options may be settled in cash or in shares of common stock, including a net issuance using shares otherwise purchasable under the option to pay the exercise price.

(Q) 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 (loss) income" in the accompanying 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 (income) expense, net" in the accompanying consolidated statements of operations. For the year ended March 31, 2026, foreign currency transaction gains were $5.1 million. For the years ended March 31, 2025 and 2024, foreign currency transaction gains were de minimis.

(R) Revenue Recognition

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

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

- *Licenses of intellectual property*: If a license to intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from the portion of the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.

- *Milestone payments*: At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.

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

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

Trade Receivables, Net

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in customer credit profiles. The Company reserves against trade receivables for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was de minimis as of March 31, 2026 and 2025. Trade receivables, net is included in "Other current assets" on the accompanying consolidated balance sheets.

(S) Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which requires 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 adopted this ASU prospectively for the fiscal year ended March 31, 2026. This resulted in expanded disclosures in line with the requirements of the ASU.

In September 2025, the FASB issued ASU 2025-07, "Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract", which refines the scope of the guidance on derivatives in ASC 815 and clarifies the guidance on share-based payments from a customer in ASC 606. This guidance is effective for fiscal years and interim periods beginning after December 15, 2026, with early adoption permitted. These requirements may be applied prospectively or on a modified retrospective basis through a cumulative-effect adjustment to the opening balance of retained earnings. The Company early adopted this guidance during the quarter ended March 31, 2026. The Company applied the derivative scope refinements guidance on a modified retrospective basis and applied the share-based payments guidance on a prospective basis. The adoption of this guidance had no impact on the Company's consolidated financial statements.

(T) Recently Issued Accounting Pronouncements

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

In November 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 expects adoption of this ASU will result in additional disclosures in line with the requirements of ASU 2024-03.

Note 3—Cash, Cash Equivalents and Marketable Securities

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

	March 31, 2026	March 31, 2025
Cash and cash equivalents		
Cash	$ 44,526	$ 93,954
Money market funds	1,374,706	2,621,457
Total cash and cash equivalents	$ 1,419,232	$ 2,715,411
Marketable securities		
Corporate bonds	$ 748,422	$ —
U.S. Treasury securities, available-for-sale	2,124,179	—
U.S. Treasury securities, held-to-maturity	—	2,171,480
Total marketable securities	$ 2,872,601	$ 2,171,480
Total cash, cash equivalents, and marketable securities	$ 4,291,833	$ 4,886,891

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

	As of March 31, 2026			
	Amortized Cost[1]	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 751,103	$ —	$ (2,681)	$ 748,422
U.S. Treasury securities	2,125,053	538	(1,412)	2,124,179
Total marketable securities, available-for-sale	$ 2,876,156	$ 538	$ (4,093)	$ 2,872,601

	As of March 31, 2025			
	Amortized Cost[1]	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities, held-to-maturity	$ 2,171,480	$ 1,267	$ (463)	$ 2,172,284

(1) Excludes $19.6 million and $12.1 million of accrued interest receivable as of March 31, 2026 and 2025, respectively, which is included in "Other current assets" on the consolidated balance sheets.

As of March 31, 2026, 129 available-for-sale marketable securities with a fair value of $1,999.6 million were in a gross unrealized loss position of $4.1 million. All marketable securities with unrealized losses had been in a loss position for less than twelve months as of March 31, 2026. The Company does not intend to sell, and is not required to sell, these securities that are in an unrealized loss position before the recovery of their amortized cost basis.

The Company classified its marketable securities as Level 2 measurements within the fair value hierarchy. The estimated fair value of available-for-sale marketable securities by contractual maturity were as follows (in thousands):

	March 31, 2026
Due within one year	$ 2,145,345
Due after one year but within five years	727,256
Total estimated fair value of available-for-sale securities	$ 2,872,601

As of March 31, 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 March 31, 2026 and 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.

The Company holds an investment in Arbutus in the form of 38,847,462 common shares of Arbutus.

The Company additionally holds an investment in Class A units of Datavant. The fair value of the Company's investment in Datavant 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 14, "Fair Value Measurements" for more information.

Summarized Equity Method Investment Details

Details regarding significant equity method investments are as follows:

	Ownership (%)		Aggregate Fair Value (in millions)	
	March 31, 2026	March 31, 2025	March 31, 2026	March 31, 2025
Datavant[1]	9%	9%	$ 233.2	$ 167.4
Arbutus	20%	20%	$ 174.8	$ 135.6

(1) The ownership percentage represents the Company's equity interest in the outstanding Class A units of Datavant. Datavant's capital structure includes 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. Refer above for additional information regarding investment.

The Company recognized unrealized (gains) losses on its significant equity method investments in the accompanying consolidated statements of operations as follows:

	Unrealized (Gain) Loss on Investment (in millions)		
	Years Ended March 31,		
	2026	2025	2024
Datavant	$ (65.8)	$ (19.8)	$ 31.1
Arbutus	$ (39.2)	$ (35.4)	$ 17.5

Summarized consolidated financial information of Datavant, reported on a one quarter lag, is as follows (in thousands):

	Twelve Months Ended December 31,		
	2025	2024	2023
Revenue	$ 1,425,992	$ 1,128,005	$ 991,107
Gross profit	$ 668,847	$ 461,521	$ 376,593
Net loss	$ (132,747)	$ (105,025)	$ (395,195)

	As of December 31,	
	2025	2024
Current assets	$ 461,460	$ 656,803
Noncurrent assets	$ 4,284,726	$ 2,340,701
Current liabilities	$ 469,057	$ 329,614
Noncurrent liabilities	$ 4,032,660	$ 1,237,271
Redeemable units	$ 241,921	$ 1,267,290

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

	Twelve Months Ended March 31,		
	2026	2025	2024
Revenue	$ 191,445	$ 6,403	$ 12,986
Income (loss) from operations	$ 156,447	$ (82,655)	$ (80,053)
Net income (loss)	$ 160,720	$ (76,571)	$ (74,385)

	As of March 31,	
	2026	2025
Current assets	$ 277,011	$ 116,808
Noncurrent assets	$ 153	$ 202
Current liabilities	$ 5,105	$ 19,431
Noncurrent liabilities	$ 11,882	$ 18,422

Note 5—Recent Transactions and Developments

(A) Global Settlement with Moderna

On March 3, 2026, the Company's subsidiary, Genevant Sciences GmbH ("Genevant"), Arbutus (together with Genevant, "Genevant/Arbutus"), and, solely for certain purposes, Genevant's parent Genevant Sciences Ltd. ("GSL"), and Moderna, Inc. and ModernaTx, Inc. (together, "Moderna") entered into a settlement agreement (the "Settlement Agreement") to resolve all patent infringement litigation between Genevant/Arbutus and Moderna pending in the U.S. and internationally relating to Moderna's unauthorized use of Genevant/Arbutus' lipid nanoparticle ("LNP") delivery technology in its vaccines, including SPIKEVAX.

Pursuant to the Settlement Agreement:

• Moderna will make a non-contingent, non-creditable, and non-refundable payment to Genevant and Arbutus of $950 million on or before July 8, 2026 (the "Fixed Payment").

• Moderna may make up to an additional $1.3 billion contingent lump sum payment (the "Contingent Payment") to Genevant and Arbutus as more fully described below.

• Moderna consented to entry of a judgment of infringement and of a judgment of no invalidity of four Genevant/Arbutus patents.

• Genevant agreed to grant Moderna a global non-exclusive license to LNP delivery technology for infectious disease applications and a covenant not to sue for certain Genevant/Arbutus patents and Moderna products.

Payments by Moderna under the Settlement Agreement will be made directly to Genevant and Arbutus consistent with the terms of a cross-license agreement (as amended, the "Cross-License Agreement") entered between Genevant (as assignee of GSL) and Arbutus. Pursuant to the Cross-License Agreement, Arbutus granted Genevant, an indirect wholly-owned subsidiary of GSL, a license under certain patents and know-how relating to Arbutus's LNP and GalNAc technologies for all applications other than hepatitis B virus and certain other excluded fields. As of March 31, 2026, RSL and Arbutus held 83% and 16%, respectively, of the issued and outstanding common shares of GSL.

Under the terms of the Cross-License Agreement, the Fixed Payment to be made by Moderna pursuant to the Settlement Agreement to Genevant/Arbutus is expected to be allocated, after deduction of litigation costs, (i) 80% to Genevant and (ii) 20% to Arbutus.

Based on this allocation, Genevant expects to receive approximately $770.2 million for its portion of the Fixed Payment, subject to adjustment upon final determination of actual litigation costs and expenses incurred. The Company accordingly recognized a gain on litigation settlement of $770.2 million during the year ended March 31, 2026 in the accompanying consolidated statements of operations and a corresponding litigation settlement receivable of $770.2 million on the accompanying consolidated balance sheets.

Moderna will make the Contingent Payment to Genevant/Arbutus (i) if the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") (whether by the initial panel, upon panel rehearing or en banc) affirms, or if there is a final non-appealable judgment that affirms, the rejection of Moderna's affirmative defense pursuant to 28 U.S.C. §1498 ("§ 1498") by the U.S. District Court for the District of Delaware in its entirety or otherwise holds that § 1498 does not bar Genevant/Arbutus' claim against Moderna as to either or both of direct infringement and indirect infringement with respect to all of the doses subject to Moderna's appeal, or (ii) upon a voluntary dismissal of Moderna's appeal (any of the foregoing under (i) or (ii), a "Genevant/Arbutus § 1498 Victory"). If the appellate court instead determines that § 1498 bars Genevant/Arbutus' infringement claims as to some, but not all, of the doses subject to Moderna's appeal, the Settlement Agreement provides that Moderna will pay Genevant/Arbutus a prorated amount of $1.3 billion, calculated based on the number of doses for which § 1498 bars Genevant/Arbutus' infringement claims as clearly articulated by the Federal Circuit, or if not clearly articulated by the Federal Circuit, as mutually agreed by the parties or determined in an accelerated binding arbitration process.

Under certain circumstances, if the Genevant/Arbutus § 1498 Victory is subsequently overturned in Moderna's favor in a final nonappealable decision, Genevant/Arbutus is required to return the Contingent Payment to Moderna, plus interest. If, following a Genevant/Arbutus § 1498 Victory, either (i) Moderna does not timely appeal such Genevant/Arbutus § 1498 Victory or (ii) such Genevant/Arbutus § 1498 Victory is subsequently affirmed in a final nonappealable decision, Moderna will have no further right to a potential repayment of the Contingent Payment.

The Contingent Payment is considered a gain contingency and was not recognized in the accompanying consolidated statements of operations for the year ended March 31, 2026. The gain will be recognized when realized or realizable.

(B) Telavant Disposition

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

Pursuant to the Stock Purchase Agreement, Roche acquired all of the issued and outstanding shares of capital stock of Telavant in exchange for approximately $7.1 billion in cash at the closing of the Roche Transaction in December 2023, as well as a one-time milestone payment of $150 million in cash, paid in August 2024 following the initiation of a Phase 3 trial in UC. The $7.1 billion in closing consideration and $150 million one-time milestone payment were 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. The Company received an upfront payment of approximately $5.2 billion in cash as its pro rata portion of the consideration upon closing of the Roche Transaction and a one-time milestone payment of approximately $110.4 million as its pro rata portion of the milestone payment following initiation of a Phase 3 trial in UC.

At the closing of the Roche Transaction, Roche acquired the full rights to further develop and manufacture RVT-3101 and commercialize it in the U.S. and Japan. Outside of the U.S. and Japan, Pfizer holds commercialization rights. In addition, following the closing of the Roche Transaction, Roche acquired Telavant's option to enter into a global collaboration with Pfizer on a next generation p40/TL1A directed bispecific antibody.

The Telavant entity that was sold did not meet the definition of a business, and therefore the Company concluded that the Roche Transaction was a sale of non-financial assets, with control transferred at closing. The sale of Telavant did not meet the criteria for reporting discontinued operations as the sale does not represent a strategic shift in the Company's business. The Company recognized a gain on sale of Telavant net assets of approximately $5.3 billion during the year ended March 31, 2024 in the accompanying consolidated statements of operations. The gain does not include the Company's portion of the one-time milestone payment, which was recognized when the milestone was achieved in June 2024. Accordingly, the Company recognized a gain on sale of Telavant net assets of $110.4 million for its pro rata portion of the one-time milestone payment during the year ended March 31, 2025. The gain on sale of Telavant net assets qualifies under the substantial shareholding exemption in the United Kingdom ("U.K.") and consequently is not subject to the corporation income tax. The following table summarizes the calculation of the gain recognized during the year ended March 31, 2024 (in thousands).

Consideration:	
Upfront cash payment	$ 5,234,373
Carrying amount of noncontrolling interest derecognized	87,500
Total consideration	**5,321,873**
Assets sold	3,253
Liabilities transferred	29,790
Net liabilities sold	**(26,537)**
Gain on sale of Telavant net assets	**$ 5,348,410**

The pretax loss generated by Telavant was $71.1 million for the period from April 1, 2023 to the Transaction Date and $101.9 million for the period from inception on November 14, 2022 to March 31, 2023. The entirety of the Telavant pretax losses was attributable to the Company.

(C) Asset Acquisition

In July 2023, Pulmovant Inc. ("Pulmovant"), a wholly-owned subsidiary of the Company, in-licensed certain intellectual property rights in exchange for a $14.0 million upfront cash payment. The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The acquired rights represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded $14.0 million as acquired in-process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2024.

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

Note 6—Discontinued Operations

Dermavant Transaction

On October 28, 2024, the Company completed the sale of its entire equity interest in its majority-owned subsidiary, Dermavant, to Organon.

Pursuant to the Merger Agreement, Organon agreed to acquire Dermavant for aggregate cash consideration comprising (i) a payment of $175.0 million payable at the closing of the Dermavant Transaction, subject to certain adjustments, (ii) a $75.0 million milestone payment payable upon FDA approval of VTAMA (the "Product") for the treatment of atopic dermatitis (the "AD Approval Milestone") and (iii) up to $950.0 million in additional milestone payments payable upon achievement of certain tiered net sales amounts (each less than or equal to $1.0 billion) with respect to the Product. Additionally, Organon agreed to make tiered royalty payments of (x) low-to-mid single digit percentages with respect to annual net sales of the Product up to $1.0 billion and (y) 30% with respect to annual net sales of the Product above $1.0 billion. Such consideration and royalty payments are subject to certain post-closing adjustments and are payable to all of Dermavant's equity holders, including holders of Dermavant RSUs, options and warrants, on a pro rata basis relative to their ownership of Dermavant prior to the closing of the Dermavant Transaction (in each case, after giving effect to the liquidation preference of Dermavant's preference shares, all of which are held by the Company, and otherwise in accordance with the applicable terms of such securities). Under the liquidation preference of Dermavant's preference shares, the Company is entitled to receive 100% of the first $270.0 million of consideration paid pursuant to the Merger Agreement. The Company received $183.6 million in cash in October 2024 upon the closing of the Dermavant Transaction, subject to certain post-closing adjustments that are not expected to be significant. The AD Approval Milestone was achieved in December 2024, and the Company received payment of the $75.0 million AD Approval Milestone in January 2025, pursuant to the terms of the Merger Agreement.

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

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

Financial results of Dermavant through closing of the Dermavant Transaction are presented as "Income (loss) from discontinued operations, net of tax" in the accompanying consolidated statements of operations for the years ended March 31, 2025 and 2024. As a result of the Dermavant Transaction, the Company recognized a gain of $376.5 million for the year ended March 31, 2025, of which $301.5 million was recognized upon the deconsolidation of Dermavant and $75.0 million was subsequently recognized upon achievement of the first milestone.

The following table presents components of discontinued operations related to the Dermavant Transaction included in "Income (loss) from discontinued operations, net of tax" (in thousands):

	Years Ended March 31,	
	2025	2024
Product revenue, net	$ 41,599	$ 75,057
License, milestone and other revenue	33,838	17,025
Revenue, net	75,437	92,082
Operating expenses:		
Cost of revenues	12,116	13,961
Research and development	24,307	61,827
Selling, general and administrative	119,879	271,310
Total operating expenses	156,302	347,098
Loss from operations	(80,865)	(255,016)
Gain on sale of subsidiary interests[1]	(376,506)	—
Change in fair value of debt	(97,322)	32,105
Interest expense[2]	30,556	34,778
Other income, net	(11,257)	(7,473)
Income (loss) from discontinued operations before income taxes	373,664	(314,426)
Income tax expense	634	721
Income (loss) from discontinued operations, net of tax	$ 373,030	$ (315,147)
Loss from discontinued operations before income taxes attributable to noncontrolling interests	$ (155)	$ (1,367)
Income (loss) from discontinued operations before income taxes attributable to Roivant Sciences Ltd.	373,819	(313,059)
Income (loss) from discontinued operations before income taxes	$ 373,664	$ (314,426)

(1) Gain on sale of subsidiary interests includes the release of accumulated other comprehensive loss of $19.9 million, primarily associated with the realization of Dermavant's cumulative translation adjustments.

(2) 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. Additionally, for the year ended March 31, 2025, interest expense includes an $8.8 million loss on extinguishment of the Credit Facility.

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

	Years Ended March 31,	
	2025	2024
Gain on sale of subsidiary interests	$ (376,506)	$ —
Share-based compensation	$ 9,666	$ 12,163
Change in fair value of debt	$ (97,322)	$ 32,105
Loss on extinguishment of debt	$ 8,848	$ —
Depreciation and amortization	$ 6,739	$ 11,457

Note 7—Certain Balance Sheet Components

Accrued Expenses

Accrued expenses at March 31, 2026 and 2025 consisted of the following (in thousands):

	March 31, 2026	March 31, 2025
Research and development expenses	$ 92,749	$ 45,813
Compensation-related expenses	87,325	53,928
Other expenses	25,749	14,553
Total accrued expenses	$ 205,823	$ 114,294

As of March 31, 2026, accrued research and development expenses included an accumulated accrual of $42.5 million of non-cancelable contractual costs as a result of the discontinuation of batoclimab, of which $39.0 million was recognized as research and development expense during the year ended March 31, 2026.

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 March 31, 2026, the Company had $400.0 million of remaining capacity available under the ATM Facility.

(B) Share Repurchase Program

The Company's board of directors has authorized various share repurchase programs, including a $1.5 billion (excluding fees and expenses) program that was completed in June 2025 and a subsequent program authorized in June 2025 and subsequently increased in March 2026, allowing for aggregate repurchases up to $1.0 billion (excluding fees and expenses). As of March 31, 2026, approximately $890.3 million remains available for share repurchases. During the year ended March 31, 2026, the Company repurchased 24,225,812 shares (including 270,000 common shares with a trade date of March 31, 2025 that settled on April 1, 2025) for an aggregate purchase price of approximately $318.1 million (including fees and expenses). During the year ended March 31, 2025, the Company repurchased 128,361,786 shares for an aggregate purchase price of approximately $1.3 billion (including fees and expenses), including 71,251,083 shares repurchased from Sumitomo Pharma Co., Ltd. at $9.10 per share for approximately $648.4 million.

(C) Common Share Purchase and Share Agreements

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

(D) Consolidated Vant Equity Transactions

Immunovant

In October 2023, the Company's subsidiary, Immunovant, Inc. ("Immunovant") completed an underwritten public offering of 8,475,500 shares of its common stock (including 1,526,316 shares of common stock purchased by the Company on the same terms as other investors in the offering and the full exercise of the underwriters' option to purchase 1,105,500 additional shares of common stock) at a price to the public of $38.00 per share. Concurrent with the public offering, the Company purchased 4,473,684 shares of Immunovant's common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at the same price per share as investors in the public offering of $38.00 per share. The net proceeds to Immunovant were approximately $466.7 million after deducting underwriting discounts and commissions, placement agent fees and offering expenses.

In January 2025, Immunovant entered into a share purchase agreement pursuant to which Immunovant issued 22,500,000 shares of its common stock (including 16,845,010 shares of common stock purchased by the Company) at a price of $20.00 per share in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the "IMVT PIPE"). The gross proceeds to Immunovant in the IMVT PIPE were approximately $450.0 million, of which $336.9 million related to the Company's participation.

In December 2025, Immunovant completed an underwritten offering of 26,200,000 shares of its common stock (including 16,666,666 shares of common stock purchased by RSL) at a price of $21.00 per share, for net proceeds to Immunovant of approximately $543.6 million after deducting underwriting discounts and commissions and offering expenses. Following the purchase of shares by RSL, the Company's ownership interest in Immunovant increased to approximately 56%, and the Company continues to consolidate Immunovant.

Note 9—Share-Based Compensation and Other Compensation Plans

(A) RSL Equity Incentive Plans

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the "RSL 2021 EIP") was approved and adopted in connection with the Business Combination and became effective immediately prior to closing. As of March 31, 2026, 217,186,782 of the Company's common shares were reserved for issuance under the RSL 2021 EIP. The number of common shares reserved for issuance under the RSL 2021 EIP will automatically increase on April 1 of each year by an amount equal to the lesser of (i) 5% of the common shares outstanding as of the last day of the immediately preceding fiscal year and (ii) such number of common shares as determined by the board of directors in its discretion. On February 25, 2026, the board of directors approved an evergreen increase for the fiscal year ending March 31, 2026, resulting in the number of shares available for issuance under the RSL 2021 EIP plan increasing by an amount representing 5% of the common shares outstanding as of March 31, 2025 (having previously deferred this decision from March 31, 2025). The RSL 2021 EIP has a ten-year term. The Company's employees, directors and consultants are eligible to receive incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, RSUs, PSUs, and other stock awards under the RSL 2021 EIP. At March 31, 2026, a total of 60,944,783 common shares were available for future grants under the RSL 2021 EIP.

2015 Equity Incentive Plan

As of the effective date of the RSL 2021 EIP, no further stock awards have been or will be made under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan (the "RSL 2015 EIP"). Awards outstanding under the RSL 2015 EIP remain subject to the terms of the RSL 2015 EIP and the applicable award agreement.

Stock Options and Performance Stock Options

Activity for stock options and performance stock options under the Company's equity incentive plans for the year ended March 31, 2026 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2025	139,412,098	$ 8.46	4.69	$ 384,006
Granted	2,264,315	$ 10.69		
Exercised	(64,389,618)	$ 10.60		
Forfeited/Canceled	(1,194,802)	$ 9.36		
Options outstanding at March 31, 2026	76,091,993	$ 6.71	5.45	$ 1,596,933
Options exercisable at March 31, 2026	69,594,586	$ 6.51	5.24	$ 1,474,526

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable options and the fair value of the Company's common stock at March 31, 2026. At March 31, 2026, total unrecognized compensation expense related to non-vested stock options was approximately $30.3 million and is expected to be recognized over a weighted-average period of approximately 1.65 years. All performance stock options have been fully expensed as of December 2023.

The Company estimated the fair value of each stock option on the date of grant using the Black-Scholes closed form option-pricing model applying the weighted average assumptions in the following table. No performance stock options were granted during the years ended March 31, 2026, 2025 and 2024.

	Years Ended March 31,		
Assumptions	**2026**	**2025**	**2024**
Expected stock price volatility	53.99%	70.52%	72.22%
Expected risk free interest rate	4.00%	4.52%	3.72%
Expected term, in years	6.18	6.21	6.21
Expected dividend yield	—%	—%	—%

Additional information regarding stock options and performance stock options is set forth below (in thousands, except per share data).

	Years Ended March 31,		
	2026	**2025**	**2024**
Intrinsic value of options exercised	$ 645,161	$ 90,542	$ 68,673
Grant date fair value of options vested	$ 86,810	$ 100,639	$ 157,359
Weighted-average grant date fair value per share of stock options granted	$ 5.95	$ 7.22	$ 5.98

Restricted Stock Units

Activity for RSUs under the Company's equity incentive plans for the year ended March 31, 2026 was as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2025	14,119,949	$ 9.63
Granted	6,473,525	$ 10.84
Vested	(5,946,593)	$ 9.01
Forfeited	(2,040,870)	$ 9.18
Non-vested balance at March 31, 2026	12,606,011	$ 10.62

The total fair value of RSUs vested during the years ended March 31, 2026, 2025 and 2024 was $53.6 million, $49.3 million and $49.1 million, respectively. RSUs vest upon the achievement of time-based service requirements.

At March 31, 2026, total unrecognized compensation expense related to non-vested RSUs was approximately $115.8 million. Unrecognized compensation expense relating to RSUs is expected to be recognized over a weighted-average period of approximately 3.09 years.

Performance Restricted Stock Units

Activity for PSUs under the Company's equity incentive plans for the year ended March 31, 2026 was as follows:

	Number of PSUs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2025	36,872,465	$ 9.35
Granted	11,900,000	$ 7.15
Forfeited[(1)]	(585,229)	$ 4.76
Non-vested balance at March 31, 2026	48,187,236	$ 8.86

(1) During the year ended March 31, 2026, 585,229 PSUs originally granted in 2016 and 2017 under the Company's now-expired 2015 Restricted Stock Unit Plan were forfeited.

During the years ended March 31, 2026, 2025 and 2024, no PSUs vested. The vesting of PSUs requires that certain performance or market conditions be achieved during the performance period. Refer below for details regarding the achievement of the Performance Condition (defined below) for certain tranches of the PSUs granted pursuant to the Senior Executive Compensation Program (defined below).

At March 31, 2026, total unrecognized compensation expense related to non-vested PSUs was approximately $205.4 million. Unrecognized compensation expense relating to PSUs, excluding those deemed improbable of vesting as of March 31, 2026, is expected to be recognized over a weighted-average period of approximately 1.04 years.

Senior Executive Compensation Program

In July 2024, the Compensation Committee of the board of directors approved a multi-year incentive compensation program for each of Matthew Gline, Chief Executive Officer; Mayukh Sukhatme, President and Chief Investment Officer; and Eric Venker, President and Chief Operating Officer. The program primarily consists of two key components: (i) one-time cash retention awards (refer below for further details regarding the one-time cash retention awards) and (ii) long-term equity incentive awards granted in the form of PSUs with both a performance- and a time-vesting component, time-vesting RSUs and time-vesting stock options. In July 2025, the board of directors appointed Frank Torti as an executive officer of the Company with the title President and Vant Chair. In connection with this appointment, the Compensation Committee approved a compensation package for Dr. Torti consisting of the same key components and with PSU and RSU awards approved on the same terms as those awarded in July 2024. Collectively, these compensation arrangements are referred to herein as the "Senior Executive Compensation Program."

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

Executive	Title	Performance Restricted Stock Units (at max)	Restricted Stock Units	Stock Options
Matthew Gline	Chief Executive Officer	14,450,000	2,754,821	—
Mayukh Sukhatme	President and Chief Investment Officer	17,000,000	1,836,547	—
Eric Venker	President and Immunovant CEO	*	204,000	409,000
Frank Torti	President and Vant Chair	11,900,000	1,836,547	—

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

The stock options and performance stock options table above includes the stock options granted to Dr. Venker pursuant to the Senior Executive Compensation Program with a total grant date fair value of $2.9 million. The Performance Restricted Stock Units and Restricted Stock Units tables above include the PSUs granted to Mr. Gline, Dr. Sukhatme and Dr. Torti and the RSUs granted to Mr. Gline, Dr. Sukhatme, Dr. Venker and Dr. Torti pursuant to the Senior Executive Compensation Program with total grant date fair values of $363.3 million and $72.7 million, respectively.

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

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

During the year ended March 31, 2026, the share price hurdles for the first five of the six vesting tranches of the PSUs granted pursuant to the Senior Executive Compensation Program were met as a result of the Company's 30-Day VWAP exceeding the specified share price hurdles of $15.00, $17.50, $20.00, $22.50 and $25.00. As a result, the "Performance Condition" applicable to the PSUs was satisfied for 28,051,785 PSUs.

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

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

	Years Ended March 31,	
Assumptions	**2026**	**2025**
Expected stock price volatility	50.0%	70.0%
Expected risk free interest rate	3.9%	4.1%
Stock price on date of grant	$ 11.40	$ 10.80

As the PSUs are subject to the market performance of the Company's stock price, share-based compensation expense is recognized over the requisite service period regardless of whether the market condition is ultimately satisfied, subject to continued service over the period. The Company has not recognized share-based compensation expense for potential PSU awards to Dr. Venker as these PSUs have not been granted by the Compensation Committee of the board of directors.

Capped Value Appreciation Rights

March 2020 CVAR Grants

The CVARs granted in March 2020 settled into a number of common shares equal to the excess of (a) the lesser of (i) the fair market value of a common share as of the settlement date or (ii) the cap of $12.68, over (b) the hurdle price of either $6.40 or $11.50, as applicable to each grant. CVARs with the lower hurdle price of $6.40 were subject to a condition (the "Knock-In Condition") pursuant to which in the event the fair market value of a common share was greater than $6.40 per share but less than $9.20 per share as of the relevant date of determination, the award of CVARs remained outstanding unless and until the Knock-In Condition was satisfied as of any applicable monthly measurement date before the expiration date of the CVARs.

In the event any CVARs satisfied the time-based service and liquidity event vesting requirements ("service-vested CVARs") but had not satisfied the hurdle price on an applicable measurement date, then such CVARs remained outstanding and the applicable award holder was provided the right to earn such CVARs if the hurdle price was satisfied on subsequent annual "hurdle measurement dates" prior to the original expiration date of the CVARs, being March 31, 2026. The "hurdle measurement dates" were March 30 of each of years 2023 through 2026. If the hurdle price is not satisfied on any such subsequent annual hurdle measurement date prior to the expiration date of the CVARs, then the CVARs would be forfeited in their entirety on the expiration date.

During the year ended March 31, 2026, all 17,548,368 service-vested CVARs previously outstanding as of March 31, 2025 satisfied their applicable hurdle price on the applicable hurdle measurement date of March 30, 2026. As a result, 422,216 common shares were issued upon the net settlement of these CVARs in April 2026. As of March 31, 2026, no CVARs granted in March 2020 remain outstanding. All March 2020 CVARs were entirely service-vested as of December 2023, and as such, have been fully expensed since December 2023. The total fair value of CVARs that service-vested during the year ended March 31, 2024 was $2.1 million.

November 2021 CVAR Grants

In November 2021, the Company made one-time grants of 6,317,350 CVARs in the aggregate under the RSL 2021 EIP to eligible participants. The CVARs are eligible to vest based on the satisfaction of service-based and performance-based vesting requirements. The performance-based vesting requirement was achieved in December 2021. Vested CVARs will be settled in common shares, up to a specified cap price.

Activity for CVARs under the RSL 2021 EIP for the year ended March 31, 2026 was as follows:

	Number of CVARs	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2025	348,527	$ 4.89
Vested	(297,795)	$ 4.99
Forfeited	(50,732)	$ 4.28
Non-vested balance at March 31, 2026	—	$ —

The total fair value of CVARs that vested during the years ended March 31, 2026, 2025 and 2024 was $1.5 million, $5.9 million and $6.2 million, respectively. During the year ended March 31, 2026, 297,795 common shares were issued upon their settlement.

(B) Employee Stock Purchase Plan

In September 2021, the Company adopted the Roivant Sciences Ltd. Employee Stock Purchase Plan (the "RSL ESPP"), which provides eligible employees, as defined by the RSL ESPP, the opportunity to purchase stock under the RSL ESPP at a price equal to 85% of the lower of the closing price on (i) the first trading day, or (ii) the last trading day of each offering period. Contributions under the RSL ESPP are limited to a maximum of 15% of an employee's base salary during the offering period and an annual maximum of $25 thousand. The Company opened enrollment in August 2022 for a three-month initial offering period, beginning October 2022, with additional six-month offering periods following thereafter.

During the years ended March 31, 2026, 2025 and 2024, 121,724, 118,640 and 140,227 common shares were purchased and issued under the RSL ESPP, respectively. Share-based compensation expense recorded was approximately $0.4 million, $0.5 million and $0.5 million for the years ended March 31, 2026, 2025 and 2024, respectively.

(C) 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 $83.4 million, $56.1 million and $54.9 million for the years ended March 31, 2026, 2025 and 2024, respectively, related to subsidiary EIPs. At March 31, 2026, total unrecognized compensation expense related to subsidiary equity was approximately $97.0 million.

(D) Priovant Share Exchange

In November 2025, the Company offered certain holders of vested equity of the Company's subsidiary, Priovant Holdings, Inc. ("Priovant"), the opportunity to exchange a portion of their vested equity granted under the Priovant 2021 Equity Incentive Plan for RSL common shares granted under the RSL 2021 EIP (the "Exchange Offer"). The Exchange Offer expired on December 23, 2025. On December 23, 2025, immediately following the expiration of the Exchange Offer, the exchanged Priovant equity instruments were canceled, and the Company granted 1,746,194 RSL common shares, under the RSL 2021 EIP, to the individuals participating in the Exchange Offer. The Exchange Offer was treated as a modification for accounting purposes and resulted in incremental share-based compensation expense of $25.2 million, of which $8.3 million was recognized to research and development expense and $16.9 million was recognized to general and administrative expense. This incremental expense was recognized in full on December 23, 2025.

(E) 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 years ended March 31, 2026, 2025 and 2024, the Company recognized general and administrative expense of $4.5 million, $21.2 million and $35.6 million, respectively, and research and development expense of $0.9 million, $5.8 million and $9.9 million, respectively, relating to the Cash Bonus Program.

(F) Senior Executive Compensation Program Cash Awards

Pursuant to the Senior Executive Compensation Program, the Company paid the following one-time cash retention awards to the officers listed in the table below:

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
Frank Torti	President and Vant Chair	$ 7,500

As a result of the cash retention rewards, the Company recognized general and administrative expense of $14.8 million and $86.4 million during the years ended March 31, 2026 and 2025.

Note 10—Income Taxes

The (loss) income before income taxes and the related expense are as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
(Loss) income before income taxes:			
Bermuda[1]	$ 62,366	$ (80,590)	$ 5,189,812
United States	(354,509)	(174,763)	(232,592)
Switzerland	21,711	(426,478)	(389,948)
Other	5,854	241	584
Total (loss) income from continuing operations before income taxes	$ (264,578)	$ (681,590)	$ 4,567,856

(1) Primarily entities which are centrally managed and controlled in the U.K. and are subject to U.K. taxes.

	Years Ended March 31,		
	2026	2025	2024
Current taxes:			
Bermuda	$ —	$ —	$ —
United States[1]	53,467	48,174	21,813
Switzerland	79,889	—	—
Other	(27)	—	(310)
Total current tax expense	$ 133,329	$ 48,174	$ 21,503
Deferred taxes:			
Bermuda	$ —	$ —	$ —
United States	—	—	—
Switzerland	—	—	—
Other	—	—	—
Total deferred tax benefit	$ —	$ —	$ —
Total income tax expense	$ 133,329	$ 48,174	$ 21,503

(1) Inclusive of the state and local income taxes.

Cash payments by jurisdiction, net of refunds, were as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
United States Federal	48,638	59,389	10,409
Other	(269)	2,521	1,945
Total	$ 48,369	$ 61,910	$ 12,354

A reconciliation of income tax expense computed at the Bermuda statutory rate to income tax expense reflected in the consolidated financial statements for the year ended March 31, 2026, pursuant to the new disclosure requirements of ASU 2023-09, is as follows (in thousands, except percentages):

	Year Ended March 31, 2026	
Income tax benefit at Bermuda statutory tax rate [1]	$ —	— %
Foreign Tax Effects		
United Kingdom		
Statutory tax rate difference between Bermuda and U.K.	$ 16,177	(6.1)%
Nondeductible/(nontaxable) changes in the fair value of investments and loss from equity method investments	(27,488)	10.4%
Taxable intercompany income/(deductible intercompany expense)	(123,074)	46.5%
Nontaxable income	(16,606)	6.3%
Nondeductible changes in the fair value of the Earn-Out Shares	11,926	(4.5%)
Valuation allowance	142,562	(53.9)%
Other	(3,524)	1.3%
Switzerland		
Statutory tax rate difference between Bermuda and Switzerland	2,086	(0.8)%
Cantonal and communal taxes [2]	39,289	(14.8)%
Deductible federal taxes	(13,590)	5.1 %
Intercompany reorganization	138,465	(52.3)%
Valuation allowance	(112,256)	42.4 %
Reversal of certain deferred tax assets[3]	25,351	(9.6)%
Other	544	(0.2)%
United States		
Statutory tax rate difference between Bermuda and the U.S.	(74,930)	28.3 %
Nondeductible executive compensation	60,323	(22.8)%
Tax deficiencies (excess tax benefits) from stock-based compensation	(34,482)	13.0 %
Taxable intercompany income/ (deductible intercompany expense)	160,909	(60.8)%
Foreign-derived intangible income	(26,310)	9.9 %
Income/(loss) from disregarded entities	(64,511)	24.4 %
Research tax credits	(20,336)	7.7 %
Valuation allowance	44,916	(17.0)%
Other	7,888	(2.9)%
Total income tax expense	$ 133,329	(50.4)%

(1) The Company's country of domicile is Bermuda, as we are legally incorporated there, and therefore have applied its 0% statutory rate.

(2) The taxes in Swiss canton of Basel-Stadt made up the majority of the state tax effect in this category (greater than 50%)

(3) Primarily relates to deferred tax assets associated with entities no longer included in the consolidated financial statements (i.e. sold, deconsolidated, or liquidated) and Switzerland expiring net operating losses.

The Company's effective tax rate for the year ended March 31, 2026 was (50.4)% and is driven by our fluctuating earnings by legal entity in various jurisdictions over the period and a valuation allowance that eliminates the Company's global net deferred tax assets. The jurisdictional earnings were significantly impacted by the income associated with the gain on litigation settlement, refer to Note 5, "Recent Transactions and Developments." The effective tax rate was also driven by the impacts of taxable intercompany income and non-deductible executive compensation.

The effective tax rate reconciliation for the year ended March 31, 2026 is presented in accordance with ASU 2023-09, while the effective tax rate reconciliations for the years ended March 31, 2025 and 2024 have not been recast and continue to be presented under the prior guidance. As a result of the adoption of ASU 2023-09, certain items in the effective tax rate reconciliation may have been reclassified between categories compared to prior periods; however, such reclassifications did not have a material impact on any individual line items or the overall effective tax rate.

A reconciliation of income tax expense computed at the Bermuda statutory rate to income tax expense reflected in the consolidated financial statements, for the years ending March 31, 2025 and 2024, are as follows (in thousands, except percentages):

	Year Ended March 31, 2025		Year Ended March 31, 2024	
Income tax expense at Bermuda statutory tax rate	$ —	— %	$ —	— %
Foreign rate differential[1]	(112,413)	16.5 %	1,196,877	26.2 %
Permanent disallowed IPR&D	—	— %	—	— %
Tax effect of changes in the fair value of investments and loss from equity method investments	(12,813)	1.9 %	15,431	0.3 %
Substantial shareholding exemption	(27,597)	4.0 %	(1,337,102)	(29.3)%
Nondeductible executive compensation	54,558	(8.0)%	19,727	0.4 %
Tax deficiencies (excess tax benefits) from stock-based compensation	(16,676)	2.4 %	(21,668)	(0.5)%
Other permanent adjustments	37,096	(5.4)%	40,085	0.9 %
Research tax credits	(31,840)	4.7 %	(22,863)	(0.5)%
Valuation allowance	134,855	(19.8)%	43,754	1.0 %
Reversal of certain deferred tax assets[2]	25,062	(3.7)%	87,262	2.0 %
Other	(2,058)	0.3 %	—	— %
Total income tax expense	$ 48,174	(7.1)%	$ 21,503	0.5 %

(1) Primarily related to operations in the U.S., Switzerland, the U.K., and other jurisdictions with statutory tax rates different than the Bermuda rate.

(2) Primarily relates to deferred tax assets associated with entities no longer included in the consolidated financial statements (i.e., sold, deconsolidated or liquidated) and Switzerland expiring net operating losses.

The Company's effective tax rate for the years ended March 31, 2025 and 2024 was (7.1)% and 0.5%, respectively. The effective tax rate for the year ended March 31, 2025 is driven by earnings by jurisdiction and a valuation allowance that eliminates the Company's global net deferred tax assets. The effective tax rate for the year ended March 31, 2024 is driven by the Company's gain on sale of Telavant net assets, which qualifies for the substantial shareholding exemption in the U.K. and consequently is not subject to the corporation income tax, as well as earnings by jurisdiction and a valuation allowance that eliminates the Company's global net deferred tax assets.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2026 and 2025 are as follows (in thousands):

	March 31, 2026	March 31, 2025
Deferred tax assets		
Research tax credits	$ 76,810	$ 54,101
Intangible assets	8,732	16,939
Capitalized research and development	189,355	41,387
Net operating loss	550,011	469,339
Share-based compensation	35,167	103,515
Lease liabilities	22,622	21,687
Other assets	33,870	18,001
Subtotal	916,567	724,969
Valuation allowance	(897,209)	(701,219)
Deferred tax liabilities		
Depreciation	(2,593)	(561)
Right-of-use assets	(15,848)	(19,270)
Other liabilities	(917)	(3,919)
Total deferred tax assets/(liabilities)	$ —	$ —

The Company has net operating losses in Switzerland, the U.S. and the U.K. in the amount of $1,512.9 million, $890.7 million and $613.4 million, respectively. The Switzerland net operating losses will expire in varying amounts between March 31, 2027 and March 31, 2032. The U.S. net operating losses can be carried forward indefinitely with utilization limited to 80% of future taxable income for tax years beginning on or after January 1, 2021, while the U.K. and other net operating losses can be carried forward indefinitely as well, with an annual limitation on utilization. The Company has $66.0 million of federal research tax credit carryforwards in the U.S., which will expire in varying amounts between March 31, 2039 and March 31, 2046. Additionally, credits of $10.8 million are related to various states and Canada.

In January 2026, Immunovant completed an internal reorganization and transfer of intellectual property rights related to their product candidates, between two of its wholly-owned subsidiaries. Ownership and rights to such intellectual property remain with Immunovant and its subsidiaries. Immunovant utilized a significant portion of their Switzerland net operating loss carryforwards to offset the impacts of the internal reorganization. Further, the internal reorganization generated deferred tax assets related to capitalized research and development expenses that will be deductible in the U.S. in future periods.

The Company assesses the realizability of the 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 record a valuation allowance as necessary. Due to the Company's cumulative loss position (exclusive of the gain on sale of Telavant net assets) which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of $897.2 million as of March 31, 2026, representing the portion of the deferred tax asset that is not more likely than not to be realized. For the period April 1, 2025 through March 31, 2026, the valuation allowance increased by $196.0 million, primarily as a result of corresponding increases in our global net operating losses. The amount of the deferred tax asset considered realizable could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of deferred tax assets at each balance sheet date in order to determine the amount, if any, required for a valuation allowance.

There are outside basis differences related to the Company's investment in subsidiaries for which no deferred taxes have been recorded, as these would not be subject to tax on repatriation, as Bermuda has no tax regime for Bermuda exempted limited companies, and the U.K. tax regime relating to company distributions and sales generally provides for exemption from tax for most overseas profits, subject to certain exceptions.

The Company is subject to tax and is required to file U.S., U.K. and Switzerland federal income tax returns, as well as income tax returns in various state, local and foreign jurisdictions. The Company is subject to tax examinations for tax years ended March 31, 2019 and forward in major taxing jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however, the potential tax benefits may impact the results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire.

The Company's unrecognized tax benefit activity during the years ended March 31, 2026, 2025 and 2024 were not material to the Company's consolidated financial statements. No interest and penalties related to unrecognized tax benefits were recorded as of March 31, 2026, 2025 or 2024.

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. The impact of the OBBBA on the Company's accompanying consolidated financial statements is not material to the Company's effective tax rate.

Note 11—Leases

The Company's operating leases consist primarily of real estate leases, including those entered into by certain wholly owned and majority-owned or controlled subsidiaries of RSL.

In September 2024, the Company's subsidiary, Roivant Sciences, Inc. ("RSI"), entered into a lease agreement with One Penn Plaza LLC for office space in New York, NY to serve as the new U.S. corporate headquarters of RSI (the "One Penn Lease"). The One Penn Lease commenced in December 2024 and will expire in August 2041. The lease contains an option to early terminate in August 2036 and an option to extend the term for one additional period of 5 years or 10 years at then-market rates in August 2041. The options to early terminate or extend the lease term were not included in the lease term as it was not reasonably certain that they would be exercised at lease commencement. The lease is classified as an operating lease and includes a period of free rent and tenant improvement incentives. Upon lease commencement, the Company recognized an operating right-of-use asset and lease liability of approximately $49.1 million, net of lease incentives received.

During the three months ended December 31, 2025, in connection with the relocation of the U.S. corporate headquarters of Roivant Sciences, Inc. and the execution of a sublease agreement, the Company identified a triggering event for the associated operating lease right-of-use asset and leasehold improvements (the asset group) for the former U.S. corporate headquarters. The Company determined that the asset group was not recoverable as its carrying amount exceeded the future net undiscounted cash flows expected under the sublease agreement. The Company measured the fair value of the asset group using an income approach based on a discounted cash flow methodology using significant Level 3 inputs. Key inputs used in the valuation included contractual and market-based sublease rental rates, estimated lease commencement date, transaction costs, and a discount rate of 8.5%.

As the carrying amount of the asset group exceeded its fair value, the Company recognized a total pre-tax impairment charge of $17.1 million during the year ended March 31, 2026, which is included in general and administrative expenses in the consolidated statements of operations.

The components of operating lease expense for the Company were as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
Operating lease cost	$ 16,023	$ 11,632	$ 10,648
Short-term lease cost	519	514	64
Variable lease cost	1,766	1,344	1,107
Total operating lease cost	$ 18,308	$ 13,490	$ 11,819

Information related to the Company's operating lease right-of-use assets and lease liabilities was as follows (in thousands, except periods and percentages):

	Years Ended March 31,		
	2026	2025	2024
Cash paid for operating lease liabilities	$ 10,393	$ 10,263	$ 11,561
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 9,605	$ 51,364	$ 719

	March 31, 2026	March 31, 2025	March 31, 2024
Weighted average remaining lease term (in years)	11.7	11.7	8.0
Weighted average discount rate	7.4%	7.4%	7.1%

As of March 31, 2026, maturities of operating lease liabilities were as follows (in thousands):

Years Ending March 31,	
2027	$ 11,716
2028	15,434
2029	15,601
2030	14,841
2031	15,046
Thereafter	94,356
Total lease payments	166,994
Less: present value adjustment	(59,331)
Less: tenant improvement allowance	(225)
Total lease liabilities	$ 107,438

Note 12—Commitments and Contingencies

(A) Commitments

Lease Commitments

The Company has leases, consisting primarily of real estate leases. Refer to Note 11, "Leases" for further information.

Other Commitments

The Company has entered into commitments under various asset acquisition and license agreements. Potential material future milestone and royalty payments as of March 31, 2026 pursuant to certain key asset acquisition and license agreements are as follows:

- ***Anti-FcRn franchise (Immunovant):*** up to a maximum of $420.0 million to HanAll Biopharma Co., Ltd. upon the achievement of certain regulatory and sales milestone events and tiered mid-single-digits to mid-teens royalty on net sales.
- ***Brepocitinib (Priovant):*** mid tens-of-millions sales milestone payment to Pfizer if aggregate net sales in a given year exceed a mid-hundreds-of-millions amount and tiered sub-teens royalty on net sales.
- ***Mosliciguat (Pulmovant):*** up to a maximum of $280.0 million to Bayer AG upon the achievement of certain development, regulatory and commercial milestone events and tiered high-single-digits royalty on net sales.
- ***LNP Technology (Genevant):*** up to 20% of Royalty-Related Receipts (as defined in the Cross-License Agreement).

The Company has further commitments not reflected above relating to other asset acquisition and license agreements entered and expects to enter into additional asset acquisition and license agreements in the future, which may require upfront payments and long-term commitments of capital resources.

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

As of March 31, 2026, the Company's subsidiary, Immunovant, had an accumulated accrual of $42.5 million of non-cancelable contractual costs as a result of the discontinuation of batoclimab, of which $39.0 million was recognized as research and development expense during the year ended March 31, 2026.

(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 consolidated financial statements as of March 31, 2026 and 2025.

Note 13—Earn-Out Shares, Public Warrants and Private Placement Warrants

Earn-Out Shares

In connection with the Business Combination, the Company issued the following restricted common shares on September 30, 2021:

a. 2,033,591 common shares issued 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"), subject to vesting 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 between November 9, 2021 and September 30, 2026 (the "Vesting Period"); and

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"), subject to vesting 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.

During the year ended March 31, 2026, both of the 20% Earn-Out Shares and the 10% Earn-Out Shares, which were already included in the Company's issued and outstanding share count, vested and therefore are no longer subject to forfeiture. Certain of the Earn-Out Shares remain subject to a lock-up and may not be sold until the one-year anniversary of the applicable vesting date.

Prior to vesting, the Earn-Out Shares required liability classification and were classified as "Liability instruments measured at fair value" on the accompanying consolidated balance sheets. The Earn-Out Shares liability was subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company's statements of operations. The Earn-Out Shares were remeasured upon their vesting, and these remeasurements were recognized in "Change in fair value of liability instruments" in the accompanying consolidated statements of operations. The resulting liabilities upon remeasurement, totaling $57.7 million, were reclassified to additional paid-in capital.

During the years ended March 31, 2026 and 2025, the Company recognized a loss of $47.7 million and a gain of $12.0 million, respectively, due to changes in the fair value of the Earn-Out Shares in the accompanying consolidated statements of operations.

Public Warrants and Private Placement Warrants

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

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

On August 2, 2023, the Company announced that it would redeem all Warrants that remained outstanding on September 1, 2023 (the "Redemption Date").

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

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

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

Note 14—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 March 31, 2026 and 2025, by level, within the fair value hierarchy (in thousands):

	As of March 31, 2026				As of March 31, 2025			
	Level 1	Level 2	Level 3	Balance as of March 31, 2026	Level 1	Level 2	Level 3	Balance as of March 31, 2025
Assets:								
Money market funds	$ 1,374,706	$ —	$ —	$ 1,374,706	$ 2,621,457	$ —	$ —	$ 2,621,457
Corporate bonds	—	748,422	—	748,422	—	—	—	—
U.S. Treasury securities	—	2,124,179	—	2,124,179	—	—	—	—
Investment in Datavant Class A units	—	—	233,171	233,171	—	—	167,361	167,361
Investment in Arbutus common shares	174,814	—	—	174,814	135,578	—	—	135,578
Total assets at fair value	$ 1,549,520	$ 2,872,601	$ 233,171	$ 4,655,292	$ 2,757,035	$ —	$ 167,361	$ 2,924,396
Liabilities:								
Liability instruments measured at fair value[1]	$ —	$ —	$ —	$ —	$ —	$ —	$ 9,981	$ 9,981
Total liabilities at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ 9,981	$ 9,981

(1) At March 31, 2025, Level 3 includes the fair value of the Earn-Out Shares of $10.0 million.

There were no transfers into or out of Level 3 during the years ended March 31, 2026 and 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 evaluates these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates is obtained. Changes in the fair value related to updated assumptions and estimates are recorded within the consolidated 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 is 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 years ended March 31, 2026 and 2025 were as follows (in thousands):

Balance at March 31, 2024	$ 147,526
Changes in fair value of investment in Datavant, included in net loss	19,835
Balance at March 31, 2025	167,361
Changes in fair value of investment in Datavant, included in net loss	65,810
Balance at March 31, 2026	$ 233,171

The changes in fair value of the Level 3 liabilities during the years ended March 31, 2026 and 2025 were as follows (in thousands):

Balance at March 31, 2024	$ 25,737
Changes in fair value of liability instruments, included in net loss	(15,756)
Balance at March 31, 2025	9,981
Changes in fair value of liability instruments, included in net loss	47,704
Reclassification to additional paid-in capital upon vesting of Earn-Out Shares	(57,685)
Balance at March 31, 2026	$ —

Investment in Datavant

The Company elected the fair value option to account for its investment in Datavant. The estimate of fair value for this investment was determined using the income approach, market approach, and implementation of the option pricing method ("OPM"). The income approach is based on the future expected cash flows, which are derived from certain assumptions attributable to Datavant including estimates of revenue growth rate, earnings before interest, taxes, depreciation and amortization and terminal growth rate. These expected cash flows are then discounted to their present value using a discount rate that reflects the risk and time value of money. The market approach estimates value by using valuation multiples derived from the stock prices of comparable publicly traded companies to determine the company's equity value. 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 March 31, 2026**	**As of March 31, 2025**
Volatility	90.0%	110.0%
Discount rate	11.8%	13.0%

Earn-Out Shares

Prior to vesting during the quarter ended December 31, 2025, 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 13, "Earn-Out Shares, Public Warrants and Private Placement Warrants" for additional details. Significant unobservable inputs used to calculate the fair value of the Earn-Out Shares included the following:

	Point Estimate Used
Input	**As of March 31, 2025**
Volatility	38.4%
Risk-free rate	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 March 31, 2025, the fair value of the Earn-Out Shares was $10.0 million, which was included in "Liability instruments measured at fair value" in the accompanying consolidated balance sheets.

Note 15—Net (Loss) Income per Common Share

The computation of the numerator to derive the basic and diluted net (loss) income per common share amounts presented on the face of the accompanying consolidated statement of operations are as follows (in thousands):

	Years Ended March 31,		
	2026	2025	2024
(Loss) income from continuing operations, net of tax	$ (397,907)	$ (729,764)	$ 4,546,353
Less: Loss from continuing operations, net of tax, attributable to noncontrolling interests	(98,136)	(184,598)	(116,350)
(Loss) income from continuing operations, net of tax, attributable to Roivant Sciences Ltd., basic	(299,771)	(545,166)	4,662,703
Less: Earnings allocated to subsidiary potentially dilutive common stock equivalents[1]	76,488	—	—
(Loss) income from continuing operations, net of tax, attributable to Roivant Sciences Ltd., diluted	$ (376,259)	$ (545,166)	$ 4,662,703
Income (loss) from discontinued operations, net of tax	$ —	$ 373,030	$ (315,147)
Less: Net loss from discontinued operations, net of tax attributable to noncontrolling interests	—	(155)	(1,370)
Income (loss) from discontinued operations, net of tax, attributable to Roivant Sciences Ltd., basic and diluted	$ —	$ 373,185	$ (313,777)
Net (loss) income attributable to Roivant Sciences Ltd., basic	$ (299,771)	$ (171,981)	$ 4,348,926
Net (loss) income attributable to Roivant Sciences Ltd., diluted	$ (376,259)	$ (171,981)	$ 4,348,926

[1] As a result of subsidiary net income for the year ended March 31, 2026, an adjustment was made to the diluted numerator for consolidated net (loss) income per common share to reflect the allocation of such net income to potentially dilutive common stock equivalents granted pursuant to the subsidiary EIP.

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 shares 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 shares 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 years ended March 31, 2026 and 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 loss from continuing operations.

As of March 31, 2026, 2025 and 2024, the following potentially dilutive common stock equivalents were excluded from the computation of diluted net (loss) income per common share:

	March 31, 2026	March 31, 2025	March 31, 2024
Stock options and performance stock options	76,091,993	139,412,098	54,648,258
Restricted stock units and performance restricted stock units (non-vested)	60,793,247	50,992,414	5,422,465
March 2020 CVARs[1]	—	17,548,368	17,548,368
November 2021 CVARs (non-vested)	—	348,527	249,120
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	1,170,140	4,731,198	3,924,305

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

Note 16—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 consolidated statements of operations and comprehensive (loss) income as net (loss) income. The measure of segment assets is reported on the 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:

	Years Ended March 31,		
	2026	2025	2024
Revenue	$ 8,260	$ 29,053	$ 32,713
Less:			
Cost of revenues	1,285	911	1,599
Program-specific research and development expenses:			
Anti-FcRn franchise—endocrine diseases	90,359	63,073	33,205
Anti-FcRn franchise—neurological diseases	82,515	93,224	41,060
Anti-FcRn franchise—rheumatology diseases	48,813	23,897	—
Anti-FcRn franchise—dermatology diseases	20,264	15,633	—
Anti-FcRn franchise—other clinical and nonclinical	3,367	9,327	39,811
Anti-FcRn franchise—contractual costs related to batoclimab program discontinuation	38,952	—	—
Brepocitinib	60,272	45,125	38,563
Mosliciguat	36,077	19,746	4,307
Other development and discovery programs	48,251	57,729	92,270
Research and development share-based compensation	47,867	39,780	32,400
Research and development personnel-related expenses	167,790	146,162	123,283
Other research and development expenses	37,285	36,717	35,010
Acquired in-process research and development	—	—	26,450
General and administrative share-based compensation	298,298	239,505	154,873
General and administrative personnel-related expenses	135,850	205,737	126,163
Other general and administrative expenses	176,318	146,168	135,097
Gain on sale of Telavant net assets	—	(110,387)	(5,348,410)
Gain on litigation settlement	(770,235)	—	—
Change in fair value of investments	(105,046)	(55,186)	47,973
Change in fair value of liability instruments	47,704	(15,756)	46,838
Gain on deconsolidation of subsidiaries	(11,027)	(3,108)	(32,772)
Interest income	(178,109)	(258,375)	(146,425)
Other (income) expense, net	(4,012)	10,721	13,562
Income tax expense	133,329	48,174	21,503
(Income) loss from discontinued operations, net of tax	—	(373,030)	315,147
Net (loss) income	$ (397,907)	$ (356,734)	$ 4,231,206

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 March 31, 2026, the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2026 at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management, under the supervision of and with the participation of our Principal Executive Officer and our Principal Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined under Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is designed 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.

A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of March 31, 2026. In making this assessment, management used the criteria set forth in the Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of March 31, 2026, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of March 31, 2026, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Roivant Sciences Ltd.

Opinion on Internal Control Over Financial Reporting

We have audited Roivant Sciences Ltd.'s internal control over financial reporting as of March 31, 2026, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Roivant Sciences Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of March 31, 2026, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of March 31, 2026 and 2025, the related consolidated statements of operations, comprehensive (loss) income, shareholders' equity and cash flows for each of the three years in the period ended March 31, 2026, and the related notes and our report dated May 20, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Iselin, New Jersey

May 20, 2026

ITEM 9B. OTHER INFORMATION

On March 30, 2026, Melissa Epperly, a director of RSL, entered into a trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provides for the potential sale between July 29, 2026 and June 30, 2027 of up to 71,000 common shares held by Ms. Epperly as well as up to 40% of the net number of common shares resulting from the RSU vesting event on September 10, 2026.

On March 30, 2026, Meghan FitzGerald, a director of RSL, entered into a trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provides for the potential sale between July 29, 2026 and July 1, 2027 of up to 30,000 common shares held by Ms. FitzGerald as well as up to 40% of the net number of common shares resulting from the RSU vesting event on September 10, 2026.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2026.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at investor.roivant.com/corporate-governance. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2026.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2026.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2026.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2026.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

For a list of the consolidated financial statements included herein, see "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibits

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
2.1*	Business Combination Agreement, dated as of May 1, 2021, by and among Montes Archimedes Acquisition Corp., Roivant Sciences Ltd. and Rhine Merger Sub, Inc.	10-K	001-40782	2.1	June 28, 2022
2.2*	Amendment No. 1 to the Business Combination Agreement, dated June 9, 2021, by and among Montes Archimedes Acquisition Corp., Roivant Sciences Ltd. and Rhine Merger Sub, Inc.	10-K	001-40782	2.9	June 28, 2022
2.3#†*	Agreement and Plan of Merger, dated September 17, 2024, by and among Dermavant Sciences Ltd., Organon & Co., Organon Bermuda Ltd. and Roivant Sciences Ltd.	8-K	001-40782	2.1	September 23, 2024
3.1*	Memorandum of Association of Roivant Sciences Ltd.	S-4/A	333-256165	3.1	July 1, 2021
3.2*	Amended and Restated Bye-laws of Roivant Sciences Ltd.	8-K	001-40782	3.1	October 1, 2021
4.1*	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	—	—	—	Filed herewith
10.1*	Third Amended and Restated Registration Rights Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd. and the parties thereto	10-K	001-40782	10.1	June 28, 2022

10.2*	Sponsor Support Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	10-K	001-40782	10.3	June 28, 2022
10.3#*	License Agreement, dated as of December 19, 2017, by and between HanAll Biopharma Co., Ltd. and Roivant Sciences GmbH	8-K	001-38906	10.6	December 20, 2019
10.4#*	Cross License Agreement, dated as of April 11, 2018, by and between Genevant Sciences Ltd. and Arbutus Biopharma Corporation	10-Q	001-34949	10.3	August 7, 2020
10.5#*	First Amendment to Cross License Agreement, dated as of June 27, 2018, by and among Genevant Sciences Ltd., Genevant Sciences GmbH and Arbutus Biopharma Corporation	10-Q	001-34949	10.4	August 7, 2020
10.6#*	Second Amendment to Cross License Agreement, dated as of June 27, 2018, by and among Genevant Sciences Ltd., Genevant Sciences GmbH and Arbutus Biopharma Corporation	10-Q	001-34949	10.5	August 7, 2020
10.7*	Form of Indemnity Agreement	S-4/A	333-256165	10.24	July 1, 2021
10.8*^	Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	S-4	333-256165	10.25	May 14, 2021
10.9*^	Roivant Sciences Ltd. 2021 Equity Incentive Plan	S-8	333-260173	99.1	October 8, 2021
10.10*^	Executive Employment Agreement between Roivant Sciences, Inc. and Matthew Gline, dated as of May 14, 2021	S-4	333-256165	10.28	May 14, 2021
10.11*^	Executive Employment Agreement between Roivant Sciences, Inc. and Eric Venker, dated as of May 14, 2021	S-4	333-256165	10.29	May 14, 2021
10.12*	Amendment No. 1 to the Support Agreement, dated as of June 9, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	10-K	001-40782	10.28	June 28, 2022
10.13*	Amendment No. 2 to the Support Agreement, dated as of September 30, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp., Patient Square Capital LLC and certain shareholders of Roivant Sciences Ltd.	8-K	001-40782	10.1	October 1, 2021
10.14*^	Amended & Restated Roivant Sciences Ltd. Employee Stock Purchase Plan	10-K	001-40782	10.27	June 28, 2023

10.15#*	Third Amendment to Cross License Agreement, dated December 9, 2021, by and between Genevant Sciences GmbH and Arbutus Biopharma Corporation	S-1	333-261853	10.37	December 22, 2021
10.16#†*	Investor Rights Agreement, dated as of September 13, 2021, by and among Priovant Holdings, Inc., Roivant Sciences Ltd. and Pfizer Inc.	10-K	001-40782	10.36	June 28, 2022
10.17#†*	License and Collaboration Agreement, dated as of September 13, 2021, by and between Pfizer Inc. and Priovant, Inc.	10-K	001-40782	10.37	June 28, 2022
10.18#*	Amendment No. 1 to License and Collaboration Agreement, dated as of June 10, 2022, by and between Pfizer Inc. and Priovant, Inc.	10-K	001-40782	10.38	June 28, 2022
10.19*^	Employment Agreement between Roivant Sciences, Inc. and Mayukh Sukhatme, dated as of May 19, 2020	S-1/A	333-260619	10.39	July 28, 2022
10.20*	Form of Stock Option Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.39	June 28, 2023
10.21*	Form of Restricted Stock Unit Award Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.40	June 28, 2023
10.22*	Form of Performance Option Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.41	June 28, 2023
10.23*	Form of Capped Value Appreciation Right Award Grant Notice under the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	10-K	001-40782	10.42	June 28, 2023
10.24*	Form of Stock Option Grant Notice under the Roivant Sciences Ltd. 2021 Equity Incentive Plan	10-K	001-40782	10.43	June 28, 2023
10.25*	Form of Restricted Stock Unit Award Grant Notice under the Roivant Sciences Ltd. 2021 Equity Incentive Plan	10-K	001-40782	10.44	June 28, 2023
10.26*^	Employment Agreement between Roivant Sciences, Inc. and Rakhi Kumar, dated as of June 5, 2023	10-Q	001-40782	10.44	August 9, 2024
10.27#*^	Employment Agreement between Roivant Sciences, Inc. and Richard Pulik, dated as of August 31, 2021	10-Q	001-40782	10.43	August 9, 2024
10.28#†*	License Agreement by and between Bayer Aktiengesellschaft and Pulmovant, Inc., dated as of July 27, 2023	10-Q	001-40782	10.45	November 12, 2024
10.29#†*	First Amendment to the License Agreement by and between Bayer Aktiengesellschaft and Pulmovant, Inc., dated as of September 22, 2023	10-Q	001-40782	10.46	November 12, 2024

10.30*	Form of Performance Restricted Stock Unit Award Grant Notice under the Roivant Sciences Ltd. 2021 Equity Incentive Plan	10-K	001-40782	10.36	May 29, 2025
10.31†^*	Separation Agreement and General Release between Roivant Sciences, Inc. and Rakhi Kumar	10-K	001-40782	10.37	May 29, 2025
10.32†*^	Consulting Agreement between Roivant Sciences, Inc. and Rakhi Kumar	10-K	001-40782	10.38	May 29, 2025
10.33*^	Letter of Offer for Employment between Roivant Sciences, Inc. and Jennifer Humes, dated as of February 7, 2025.	10-Q	001-40782	10.1	August 11, 2025
10.34*^	Amended & Restated Executive Employment Agreement between Roivant Sciences, Inc. and Eric Venker, dated as of July 28, 2025.	10-Q	001-40782	10.2	August 11, 2025
10.35†*^	Employment Agreement between Immunovant, Inc. and Eric Venker, dated as of July 28, 2025.	10-Q	001-40782	10.3	August 11, 2025
10.36*^	Form of Capped Value Appreciation Right Award Grant Notice and Award Agreement under 2019 Equity Incentive Plan of Immunovant, Inc.	10-Q	001-40782	10.4	August 11, 2025
10.37*^	Forms of Option Grant Notices and Option Agreements under 2019 Equity Incentive Plan of Immunovant, Inc.	10-Q	001-40782	10.5	August 11, 2025
10.38*^	2019 Equity Incentive Plan of Immunovant, Inc.	10-Q	001-40782	10.6	August 11, 2025
10.39†*^	Special Equity Award Opportunity Letter, dated as of July 26, 2024.	10-Q	001-40782	10.7	August 11, 2025
10.40#†*	Settlement Agreement, dated as of March 3, 2026, by and among Genevant Sciences GmbH, Arbutus Biopharma Corp., Genevant Sciences Ltd., Moderna, Inc. and ModernaTX, Inc.	8-K/A	001-40782	10.1	March 23, 2026
19*	Insider Trading Policy	10-K	001-40782	19	May 29, 2025
21.1	List of Subsidiaries of Roivant Sciences Ltd.	—	—	—	Filed herewith
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm of Roivant Sciences Ltd.	—	—	—	Filed herewith
24.1	Power of Attorney (included on signature page)	—	—	—	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
97*	Roivant Sciences Ltd. Compensation Recoupment Policy	10-K	001-40782	97	May 30, 2024
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 File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	Filed herewith

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

† Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

* Previously filed.

** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: 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 Annual Report on Form 10-K 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.

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Roivant Sciences Ltd.

Date: May 20, 2026 By: /s/ Keyur Parekh

Name: Keyur Parekh
Title: Authorized Signatory

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard Pulik, Jo Chen and Keyur Parekh, as their true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Matthew Gline Matthew Gline	Chief Executive Officer and Director (Principal Executive Officer)	May 20, 2026
/s/ Richard Pulik Richard Pulik	Chief Financial Officer (Principal Financial Officer)	May 20, 2026
/s/ Jennifer Humes Jennifer Humes	Chief Accounting Officer (Principal Accounting Officer)	May 20, 2026
/s/ Mayukh Sukhatme Mayukh Sukhatme	President and Chief Investment Officer and Director	May 20, 2026
/s/ Keith Manchester Keith Manchester	Director	May 20, 2026
/s/ Ilan Oren Ilan Oren	Director	May 20, 2026
/s/ Daniel Gold Daniel Gold	Director	May 20, 2026
/s/ Melissa Epperly Melissa Epperly	Director	May 20, 2026
/s/ Meghan FitzGerald Meghan FitzGerald	Director	May 20, 2026
/s/ James C. Momtazee James C. Momtazee	Director	May 20, 2026

[This page intentionally left blank]

[This page intentionally left blank]

[This page intentionally left blank]

roivant

ROIVANT.COM