



**595,134,445 Common Shares**  
**30,750,261 Common Shares Issuable Upon Exercise of Warrants**  
**10,214,365 Private Placement Warrants to Purchase Common Shares**

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This prospectus supplement supplements the prospectus dated November 9, 2021 (the “Prospectus”), which forms a part of our registration statement on Form S-1 (No. 333-260619). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our annual report on Form 10-K, filed with the Securities and Exchange Commission on June 28, 2022 (the “Annual Report”). Accordingly, we have attached the Annual Report to this prospectus supplement.

This prospectus supplement relates to the issuance by us of up to (i) 20,535,896 common shares, \$0.0000000341740141 par value per share (the “Common Shares”), that are issuable by us upon the exercise of the outstanding public warrants (the “Public Warrants”), which were previously registered, and (ii) 10,214,365 Common Shares that are issuable by us upon the exercise of the private warrants (the “Private Placement Warrants” and, collectively with the Public Warrants, the “Warrants”) originally issued in a private placement.

This prospectus supplement also relates to the potential offer and sale from time to time by the securityholders named in the Prospectus or their permitted transferees (the “Holders”) of (i) up to 595,134,445 of our Common Shares, consisting of (x) 22,000,000 Common Shares issued in the PIPE Financing (as defined herein), (y) up to 10,214,365 Common Shares issuable upon exercise of the Private Placement Warrants and (z) 562,920,080 issued and outstanding Common Shares held by certain Holders (including Common Shares underlying vested restricted share awards), and (ii) the Private Placement Warrants. We will not receive any proceeds from the sale of Common Shares or Private Placement Warrants by the Holders pursuant to the Prospectus.

Our Common Shares and Public Warrants are listed on The Nasdaq Global Market under the symbols “ROIV” and “ROIVW,” respectively. On June 27, 2022, the last reported sale price of our Common Shares was \$4.68 per Common Share and the last reported sale price of our Warrants was \$0.60 per Warrant.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

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**We are an “emerging growth company” under federal securities laws and are subject to reduced public company reporting requirements. Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 6 of the Prospectus, and under similar headings in any amendment or supplements to the Prospectus, including this prospectus supplement.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is June 28, 2022.

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, 2022

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)

Suite 1, 3rd Floor  
11-12 St. James's Square  
London SW1Y 4LB  
United Kingdom  
(Address of principal executive offices)

98-1173944  
(I.R.S. Employer  
Identification No.)

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, \$0.000000341740141 per share	ROIV	The Nasdaq Global Market
Redeemable Warrants, each whole warrant exercisable for one Common Share at an exercise price of \$11.50 per share	ROIVW	The Nasdaq Global Market

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 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.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's common shares, par value \$0.000000341740141 per share (the "Common Shares"), on The Nasdaq Global Market on October 1, 2021 was approximately \$1,115,587,985. The registrant has elected to use October 1, 2021, which was the initial trading date for the registrant's Common Shares on The Nasdaq Global Market, as the calculation date because on September 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. Common Shares held by each executive officer and director and by each other person who may be deemed an affiliate of the registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of June 21, 2022 there were 700,765,918 Common Shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement to be issued in conjunction with the registrant's 2022 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended March 31, 2022, 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.

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## 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. Unless the context otherwise requires, references in this section to “we,” “us,” “our,” “Roivant” and the “Company” refer to Roivant Sciences Ltd. and its subsidiaries and affiliates, as the context requires. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

### Risks Related to Our Business and Industry

- Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development may make it difficult for us to execute on our business model and for you to assess our future viability.
- We may never achieve or maintain profitability.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to successfully market our products, acquire or in-license new products or product candidates, complete the development and commercialization of our products and product candidates and continue to pursue our drug discovery efforts.
- We have limited experience as a commercial company and the marketing and sale of VTAMA® (tapinarof) or any future products may be unsuccessful or less successful than anticipated.
- We may not be successful in our efforts to acquire, in-license or discover new product candidates.
- We face risks associated with the allocation of capital and personnel across our businesses.
- We face risks associated with the Vant structure.
- The global pandemic resulting from the outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including the marketing of our products and our ongoing clinical trials and preclinical studies.
- Clinical trials and preclinical studies are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or preclinical studies on the expected timelines, if at all.
- Our approach to the discovery and development of product candidates from our small molecule discovery engine is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from these platforms.
- Certain of our product candidates are novel, complex and difficult to manufacture.
- Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulator may delay, limit or deny approval.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- Our products and product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.
- We depend on the knowledge and skills of our senior leaders and may not be able to manage our business effectively if we are unable to attract and retain key personnel.

- We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt operations.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology, products and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If the patent applications we hold or have in-licensed with respect to our products or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future products or product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our products.
- Patent terms and their scope may be inadequate to protect our competitive position on current and future products and product candidates for an adequate amount of time.

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

- If our performance does not meet market expectations, the price of our securities may decline.
- We have incurred and will continue to incur increased costs as a result of operating as a public company and our management has devoted and will continue to devote a substantial amount of time to new compliance initiatives.
- Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.
- Anti-takeover provisions in our memorandum of association, bye-laws and Bermuda law could delay or prevent a change in control, limit the price investors may be willing to pay in the future for our Common Shares and could entrench management.
- Our largest shareholders and certain members of our management own a significant percentage of our Common Shares and will be able to exert significant control over matters subject to shareholder approval.

#### **Forward-Looking Statements**

This 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 and Section 21E of the Exchange Act. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this 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 limited operating history and risks involved in biopharmaceutical product development;

- our limited experience as a commercial-stage company and ability to successfully commercialize VTAMA® (tapinarof);
- our ability to raise additional capital to fund our business on acceptable terms or at all;
- the fact that we will likely incur significant operating losses for the foreseeable future;
- the impact of public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) on our business (including our clinical trials and preclinical studies), operations and financial condition and results;
- our ability to acquire, in-license or discover new product candidates;
- our Vant structure and the potential that we may fail to capitalize on certain development opportunities;
- clinical trials and preclinical studies, which are very expensive, time-consuming, difficult to design and implement and involve uncertain outcomes;
- the unproven nature of our approach to the discovery and development of product candidates from our small molecule discovery engine;
- the novelty, complexity and difficulty of manufacturing certain of our products and product candidates, including any manufacturing problems that result in delays in development or commercialization of our products and product candidates;
- difficulties we may face in enrolling and retaining patients in clinical trials and/or clinical development activities;
- the results of our clinical trials not supporting our proposed claims for a product candidate;
- changes in interim, top-line and/or preliminary data from our clinical trials changing as more data becoming available or being delayed due to audit and verification process;
- changes in product manufacturing or formulation that could lead to the incurrence of costs or delays;
- the failure of any third-party we contract with to conduct, supervise and monitor our clinical trials to perform in a satisfactory manner or to comply with applicable requirements;
- the fact that obtaining approvals for new drugs is a lengthy, extensive, expensive and unpredictable process that may end with our inability to obtain regulatory approval by the FDA or other regulatory agencies in other jurisdictions;
- the failure of our clinical trials to demonstrate substantial evidence of the safety and efficacy of our products and product candidates, including, but not limited to, scenarios in which our products and product candidates may cause adverse effects that could delay regulatory approval, discontinue clinical trials, limit the scope of approval or generally result in negative media coverage of us;
- our inability to obtain regulatory approval for a product or product candidate in certain jurisdictions, even if we are able to obtain approval in certain other jurisdictions;
- our ability to effectively manage growth and to attract and retain key personnel;
- any business, legal, regulatory, political, operational, financial and economic risks associated with conducting business globally;
- our ability to obtain and maintain patent and other intellectual property protection for our technology, products and product candidates;
- the inadequacy of patent terms and their scope to protect our competitive position;
- the failure to issue (or the threatening of their breadth or strength of protection) or provide meaningful exclusivity for our current and future products and product candidates of our patent applications that we hold or have in-licensed;

- the fact that we do not currently and may not in the future own or license any issued composition of matter patents covering certain of our products and product candidates and our inability to be certain that any of our other issued patents will provide adequate protection for such products and product candidates;
- the fact that our largest shareholders (and certain members of our management team) own a significant percentage of our stock and will be able to exert significant control over matters subject to shareholder approval;
- the outcome of any pending or potential litigation, including but not limited to our expectations regarding the outcome of any such litigation and costs and expenses associated with such litigation;
- changes in applicable laws or regulations;
- the possibility that we may be adversely affected by other economic, business and/or competitive factors; and
- any other risks and uncertainties, including those described under Part 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.

**ITEM 1. BUSINESS**

*References to “Roivant,” “the Company,” “we,” “us” or “our” in the following section refer to Roivant Sciences Ltd. and its subsidiaries, unless the context otherwise requires.*

**Overview**

We are building the next-generation “big pharma” company, organized to harness modern technologies and computational tools as well as the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity.

We are a diverse team of experienced drug developers, scientists, physicians, company builders, data scientists and engineers, biopharma investors, physicists and business development professionals dedicated to improving the lives of patients. At Roivant, we combine our team’s extensive experience and multi-disciplinary expertise with innovative technologies to identify and advance potentially transformative medicines.

We deploy a hypothesis-driven approach to identify novel or clinically-validated targets and biological pathways in areas of high unmet medical need. We then seek to acquire, in-license or discover promising drug candidates against those targets or pathways. Our small molecule discovery engine is powered by leading computational physics and machine learning (“ML”) capabilities for in silico drug design.

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

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology and oncology, and modalities, including biologics, topicals and bifunctional small molecules. We have launched and taken public multiple Vants, resulting in an aggregate ownership stake of approximately \$589 million in our publicly-traded Vants as of March 31, 2022 (inclusive of the value of certain shares of Myovant Sciences Ltd. as to which Roivant has a return right under certain circumstances). The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our founding in 2014, we have:

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

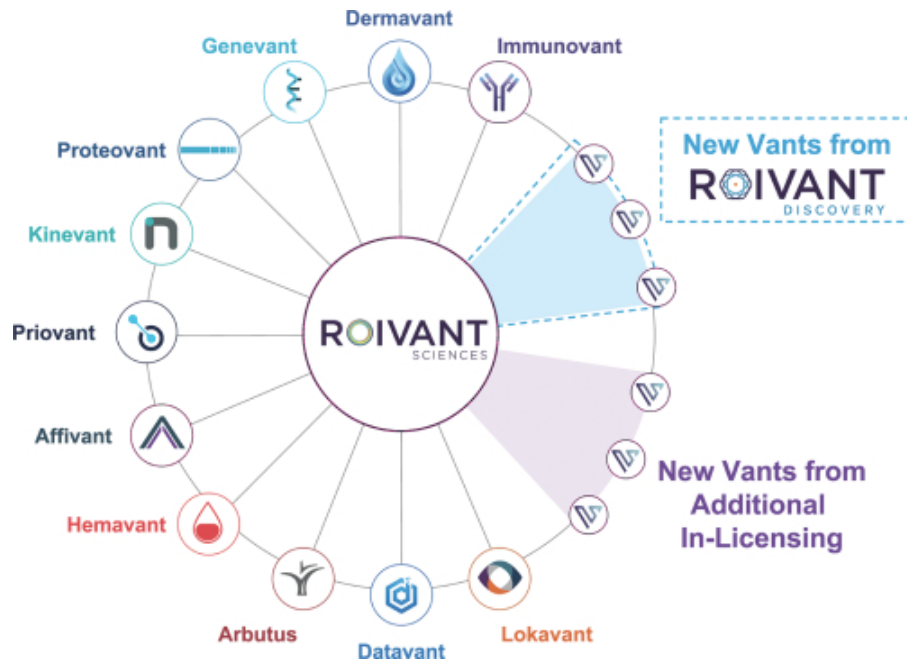


The following table summarizes selected commercial and development-stage pipeline products and product candidates.

Product/Product Candidate	Indication	Vant	Modality	Phase
VTAMA® (tapinarof)	Psoriasis	Dermavant	Topical	Commercial
VTAMA® (tapinarof)	Atopic Dermatitis	Dermavant	Topical	Phase 3
Batoclimab	Myasthenia Gravis	Immunovant	Biologic	Phase 3
Batoclimab	Thyroid Eye Disease	Immunovant	Biologic	Phase 3
Batoclimab	Warm Autoimmune Hemolytic Anemia	Immunovant	Biologic	Phase 2 or 3
Batoclimab	Other Indications	Immunovant	Biologic	Phase 2 or 3
Brepocitinib	Dermatomyositis	Priovant	Small Molecule	Phase 3
Brepocitinib	Systemic Lupus Erythematosus	Priovant	Small Molecule	Phase 2*
Brepocitinib	Other Indications	Priovant	Small Molecule	Phase 2
Namilumab	Sarcoidosis	Kinevant	Biologic	Phase 2
RVT-2001	Transfusion-Dependent Anemia in Patients with Lower-Risk MDS	Hemavant	Small Molecule	Phase 1/2
AFVT-2101	Solid Tumors	Affivant	Biologic	Preclinical

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

\* Reflects an ongoing trial that is designed to serve as one of two potentially registrational trials for brepocitinib.



We have elected to wind down the development of Aruvant’s ARU-1801 after considering the future development costs of the program, the current market environment and the clinical and commercial profile of the drug. For more information on our cost optimization and pipeline reprioritization initiative, refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments.”

As part of our mission to redefine “big pharma,” we aim to develop transformative medicines faster for diseases for which there are no approved therapies or the current standard of care treatment has significant limitations or drawbacks. We believe we are uniquely positioned to accomplish this by:

- ***Leveraging complementary approaches to identify or discover promising drug candidates:*** We assembled our current development-stage 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. In addition, our small molecule discovery engine allows us to design, optimize and validate our own novel product candidates, providing us with another avenue to pursue compelling targets or pathways and further expand our pipeline.
- ***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 products or product candidates.
- ***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.
- ***Allocating capital to maximize R&D efficiency:*** We apply an objective, rigorous decision framework across the drug development process designed to ensure resources and capital are continuously directed towards programs we believe have a higher probability of success and away from those that fail to meet our 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 a commercial drug and several drug candidates across different therapeutic areas, phases of development, modalities and geographies. This approach limits our exposure to several 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 that 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 that we are uniquely capable of maximizing value for patients and investors.
- ***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 and plans for commercialization.

Through continued investment in our model, we believe we are well-positioned to advance our current pipeline through regulatory approval and commercialization, expand our pipeline through novel drug discovery and in-licensing and acquisition transactions, and execute on our vision of transforming the delivery of healthcare to patients.

## Our Process

### Discover

We focus on developing potentially transformative medicines that address areas of significant unmet medical need. We take a hypothesis-driven approach, focusing on compelling pathways, targets and drug classes that we believe lack established leaders, and we proactively pursue or discover drugs that align with our hypotheses. We focus on building diversification and varied risk profiles into our pipeline and are agnostic to therapeutic area, stage of development and drug modality. We leverage internally developed technologies as well as a multi-disciplinary team with diverse backgrounds to evaluate the universe of targets and biological pathways that we deem compelling. Once we have built conviction around a specific target or biological pathway, we look for assets to in-license or acquire, and/or design novel drugs through our small molecule discovery engine.

Our ability to rapidly identify and execute in-licensing opportunities is underpinned by our diverse business development team, which consists of former investment professionals and experienced R&D and data scientists. Our track record in R&D and our ability to implement creative deal structures ensures that we are a favored development partner and are able to acquire assets on attractive terms with shared risk and aligned incentives. We have been successful in-licensing drugs from global pharmaceutical companies, small biotech startups and academic centers around the world, and we are proud of our deep network of academic and industry partners. Our goal is to add multiple potentially category-creating or category-leading drugs to our pipeline each year through this in-licensing strategy, a pace which is consistent with our track record over the past several years.

As a complement to our in-licensing strategy, we also apply our hypothesis-driven approach to our small molecule discovery engine, ensuring we direct our efforts toward high value pathways, targets and drug classes. We have world-leading capabilities in computational physics for drug design, with an advanced computational physics platform integrated with a proprietary supercomputing cluster and a wet-lab facility equipped for generating a broad range of experimental data. We have also built a ML platform, VantAI, tailored to the *in silico* design and optimization of novel protein degraders in development at Proteovant.

Our small molecule discovery engine has broad capabilities across multiple categories of small molecules and has three initial areas of focus:

- **Heterobifunctionals and molecular glues:** We are building an end-to-end platform for the discovery of protein degraders, a therapeutic approach with broad potential applicability to diseases associated with protein overactivity and with no incumbent leader. Our capabilities in targeted protein degradation include a long-term partnership with a leading academic lab, the ability to optimize our degraders using both computational physics and ML and our well-established clinical development capabilities.
- **Covalency:** We have assembled a team of experts in the field of chemoproteomics to build a proprietary human Disease Reactome database enabled by translational disease models to better understand the areas and opportunities around discovering and developing covalent binders of proteins. The combination of experimental data with physics-based computational methods allows us to assess relative pocket ligandability and protein high order structure to predict optimal covalent adduct structures and optimize molecules with desired reactivity.
- **Deficiency to best-in-class:** We also use our physics-based capabilities to evaluate existing small molecules—either development stage or commercially available—that have already demonstrated therapeutic potential but have well understood limitations, such as off-target effects or binding limitations, which we believe may enable us to rapidly optimize these small molecules and bring them into the clinic as potentially best-in-class candidates.

We anticipate that our small molecule discovery engine will expand our development-stage pipeline by generating candidates to advance through the launch of potential new Vants, or to integrate with existing Vants if there is appropriate therapeutic area overlap, in either case taking advantage of Roivant's established clinical development capabilities.

## Develop

We believe the Vant model accelerates successful execution due to three key factors: nimble teams, incentive alignment and robust governance. We build Vant teams with deep, relevant expertise to promote successful execution of development strategy. By keeping Vant teams focused and generally small, we strive to eliminate excessive bureaucracy, thereby facilitating rapid decision-making and ultimately accelerating outcomes. Vants are built as entrepreneurial biotech companies, where each Vant leader is compensated with significant upside potential in the form of Vant equity. By aligning employee incentives with successful Vant outcomes, we encourage Vant leaders to take calculated risks and implement strategies that we believe differentiate the speed and creativity of their development capabilities from legacy large pharmaceutical companies, where drug developers may face asymmetric downside in the event of failure and where upside equity, if granted, is diluted by many diverse projects. Vants are also supported through a robust governance structure that is centralized at Roivant. Our governance team ensures accountability for execution at Vants and allows us to capture synergies through shared technology and certain future shared commercial functions, while at the same time providing access to a broad range of Roivant resources when Vants face critical strategic questions.

## Commercialize or monetize

The Vant model is designed to maximize the value of each drug that we successfully develop and generate returns for shareholders through the independent commercialization of products, partnerships with pharmaceutical and biotechnology companies or the selective sale of Vants. Our primary objective is to launch commercial products ourselves, but we may sell or partner Vants or specific drugs based on the facts and circumstances, including, without limitation, the strategic rationale and financial return potential. In May 2022, we launched our first commercial product, VTAMA for the treatment of psoriasis.

## Our Technologies

Our platform leverages technologies that are designed to optimize each stage of the drug discovery, development and commercialization process.

Our *in silico* small molecule discovery engine at Roivant Discovery is powered by our QUASAR (QUantum, AI and Structure-Activity Relationships) capabilities.

The key components of our small molecule discovery engine include:

- ***A quantum mechanics-based molecular dynamics software platform to predict the interactions, energies and conformational behavior of targets and generate novel drug candidates.*** We can simulate hundreds of molecules per day and make predictions for drug design, enabling the optimization of properties such as binding affinity, selectivity, membrane permeability and solubility. We also have a suite of molecular dynamics and simulation tools to generate additional insights regarding individual atomic contributions to binding properties and conformational dynamics.
- ***A supercomputing cluster composed of over 800 graphics processing units.*** Our supercomputing cluster allows us to run molecular simulations at biologically meaningful timescales predicting not only affinity but also how biomolecules will respond at an atomic level to perturbations such as mutation, phosphorylation, protonation, or the addition or removal of a ligand and functionally important structural changes in proteins.
- ***A suite of degrader-specific ML tools.*** We have developed a novel protein contact-first workflow that utilizes information about known protein-protein interactions to build new degraders that can effectively stabilize target-E3 interfaces; a degron knowledge graph, which we believe to be industry-leading, to map the ubiquitin proteasome system; and a unique model, based on millions of carefully curated protein stability datapoints, to predict degradation.

- ***A wet lab fully equipped for synthetic chemistry, crystallography, biophysics, biochemistry and biology.*** Our in-house laboratories are tightly integrated with our computational physics platform to directly augment simulations with biophysical data as well as validate simulation predictions. Certain experimental techniques enable more accurate and efficient simulations on targets where we lack crystal structures. Combined with homology modeling and X-ray crystallography, this allows for the simultaneous design of chemical matter against a target while refining atomistic structural models and solving high-resolution crystal structures.

Our QUAISAR capabilities allow us to predict how molecules will interact by using principles of quantum physics and statistical mechanics to computationally model the forces and energies of molecular systems at atomic scale. Based on internal and published benchmarks, we believe that the speed and accuracy of binding free energy calculations in QUAISAR are on par with the best commercially available tool, Schrödinger’s FEP+, and superior to open-source methods. Further, we believe our ability to augment QUAISAR simulations with experimental biophysical data generated in-house creates a sustainable advantage compared to competitors, especially for complex conformational changes in biomolecules. These QUAISAR capabilities power *in silico* assays that allow us to predict binding affinity between a ligand and protein, decompose energetics into atomic contributions, predict conformational dynamics of a protein as it shifts from active to inactive states, and identify potentially novel binding sites on a protein.

As we have developed drugs in clinical trials, we have also built technologies to improve the process of running such trials. We have aggregated many of these at our subsidiary Lokavant. Lokavant’s software integrates real-time data from ongoing clinical trials and monitors risks related to time, cost and quality. Its proprietary data model serves as a “common language” for trial operational data and ensures that all trial data sources are ingested, harmonized and aggregated into a central database, allowing the trial sponsor to access operational trial data in near-real time. This approach is a substantial departure from traditional operations which typically share different types of trial data asynchronously and on multi-week delays. Algorithms trained on a proprietary dataset of operational metadata from over 2,000 trials are designed to identify the most important risks with sufficient time to empower researchers to implement interventions to mitigate those risks and deliver trial results on budget and on time. Lokavant’s software is in use in Roivant’s late stage clinical trials, as well as trials being conducted by other sponsors and contract research organizations.

In designing development and commercialization strategies for our pipeline of drugs, we also identified significant shortcomings with commercially available patient data. Today, healthcare data is siloed across multiple fragmented data sources, limiting the ability to generate a comprehensive understanding of patient health. Datavant, a company which we founded and in which we maintain a non-controlling interest, is working to address this problem. In June 2021, Datavant entered into a definitive merger agreement with Ciox Health, a leader in clinical data exchange. The combined entity, named Datavant, is the nation’s largest health data ecosystem, enabling patients, providers, payers, health data analytics companies, patient-facing applications, government agencies, and life science companies to securely exchange their patient-level data. At the closing of the transaction in July 2021, Roivant received approximately \$320 million in cash and a minority equity ownership interest in the combined entity.

We will continue to execute against our goal of building the next-generation pharmaceutical company by fully integrating modern technologies at each stage of the drug discovery, development and commercialization process. We believe that there is significant opportunity to address inefficiencies within these processes, and we expect to build technologies where we find commercially available tools nonexistent or insufficient for our needs.

## **Our Key Catalysts**

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

<u>Vant</u>	<u>Catalyst</u>	<u>Expected Timing</u>
Dermavant	Updates on commercial launch of VTAMA Topline data from VTAMA Phase 3 trials in atopic dermatitis	Ongoing 1H 2023
Immunovant	Topline data from batoclimab Phase 3 trial in MG Initiate two additional pivotal programs, including TED Announce two new indications	2H 2024 2H 2022 August 2022
Priovant	Topline data from potentially registrational brepocitinib Phase 2 trial in systemic lupus erythematosus	2H 2023
Kinevant	Topline data from namilumab Phase 2 trial in sarcoidosis	1H 2024
Hemavant	Data from RVT-2001 Phase 1/2 trial in lower-risk MDS	2H 2023

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

The below table summarizes the estimated exclusivity periods in the U.S. for select products and product candidates:

<u>Vant</u>	<u>Product or Product Candidate</u>	<u>Estimated U.S. Exclusivity / IP Coverage</u>
Dermavant	VTAMA® (tapinarof)	2038
Immunovant	IMVT-1401	Later of (i) 2035 or (ii) 12 years post U.S. approval
Priovant	Brepocitinib	2039
Kinevant	Namilumab	12 years post U.S. approval
Hemavant	RVT-2001	2036

*Note: References are to calendar years. Estimated U.S. exclusivity is based on (i) for VTAMA, the expected expiry date of the U.S. drug substance patent covering the active ingredient in VTAMA, (ii) for IMVT-1401 and namilumab, the expected expiration of U.S. regulatory exclusivity, (iii) for brepocitinib, the expected expiry date of any patent to issue from a pending application covering the crystalline form of the molecule (in addition to a composition of matter patent with an expected expiry date in 2035) and (iv) for RVT-2001, the expected expiry date of the patent covering the crystalline form of the molecule (in addition to a composition of matter patent with an expected expiry date in 2035). Exclusivity does not give effect to any potential patent term extensions. For more information, please refer to “—Intellectual Property” and “Risk Factors—Risks Related to Our Intellectual Property.”*

The table below summarizes select potential future payment obligations from acquisitions, in-licensings and subsequent financings for select products and product candidates:

<b>Vant</b>	<b>Product or Product Candidate</b>	<b>Milestones</b>	<b>Royalty</b>
Dermavant	VTAMA® (tapinarof)	<ul style="list-style-type: none"> <li>£100M (~\$126M on the date of achievement) milestone to GSK following VTAMA U.S. approval and CAD\$25M (approximately \$20M on the date of achievement) milestone to Welichem upon the first U.S. VTAMA commercial sale; to be paid using \$160M RIPSAs funding received in June 2022</li> <li>Up to CAD\$75M in remaining commercial milestones to Welichem, with CAD\$35M payable upon VTAMA first U.S. commercial sale for atopic dermatitis and the remainder payable as first commercial sales are achieved in various ex-U.S. countries</li> <li>Additional milestones owed to NovaQuest in connection with two 2018 financings that are accounted for as debt</li> </ul>	<ul style="list-style-type: none"> <li>Low single-digit to high single-digit tiered percentage of quarterly revenues based on achievement of specified net sales thresholds, up to a \$344M cap, to be paid to an investor group in exchange for \$160M RIPSAs funding received in June 2022, following VTAMA approval</li> </ul>
Immunovant	IMVT-1401	<ul style="list-style-type: none"> <li>Up to a maximum of \$442.5M upon the achievement of certain development, regulatory and sales milestone events</li> </ul>	<ul style="list-style-type: none"> <li>Tiered royalties on net sales ranging from mid-single digits to mid-teens</li> </ul>
Priovant	Brepocitinib	<ul style="list-style-type: none"> <li>Mid tens-of-millions sales milestone payment if aggregate net sales in a given year exceed a mid hundred-of-millions amount</li> </ul>	<ul style="list-style-type: none"> <li>Tiered sub-teens royalty on net sales</li> </ul>
Kinevant	Namilumab	<ul style="list-style-type: none"> <li>Up to \$40M upon the achievement of certain milestones</li> </ul>	<ul style="list-style-type: none"> <li>Tiered royalties on net sales ranging from sub-teens to mid-teens</li> </ul>
Hemavant	RVT-2001	<ul style="list-style-type: none"> <li>Up to \$65M in development and regulatory milestones for the first indication; up to \$18M in payments for each additional indication; up to \$295M in commercial milestone payments</li> </ul>	<ul style="list-style-type: none"> <li>Tiered high single-digit to sub-teens royalty on net sales</li> </ul>

*Note: The summaries above do not purport to be complete. Please refer to “—Asset Acquisition and 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.*

The table below summarizes our ownership of our subsidiary companies and certain affiliates as of March 31, 2022:

Vant	Roivant Ownership	
	Basic <sup>1</sup>	Fully Diluted <sup>2</sup>
Dermavant	100%	83%
Immunovant	63% <sup>3</sup>	58% <sup>3</sup>
Priovant	75%	70%
Proteovant	60%	54%
Genevant	83%	67%
Kinevant	88%	83%
Hemavant	100%	100%
Affivant	100%	99%
Arbutus	26% <sup>3</sup>	24% <sup>3</sup>
Lokavant	90%	84%
Datavant	*	*

Note: Excludes early-stage pipeline of protein degraders and inhibitors being developed through our small molecule discovery engine. Ownership figures as of March 31, 2022.

1. Basic ownership refers to Roivant's percentage ownership of the issued and outstanding common and preferred shares (if applicable) of the entity.

2. Fully diluted ownership refers to Roivant's percentage ownership of all outstanding equity interests of the entity, including unvested RSUs as well as options and warrants, in each case whether vested or unvested.

3. Denotes entities that are publicly traded.

\*As of March 31, 2022, the Company's minority equity interest in Datavant represented approximately 17% of the outstanding Class A units. Datavant's capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company's ownership interest would be diluted. For more information on Roivant's ownership interest in Datavant, please refer to Note 4 to Roivant's consolidated financial statements included in this Annual Report on Form 10-K.



## Dermavant Overview

- **Overview:**
  - Dermavant is marketing VTAMA® (tapinarof) cream, 1%, for the topical treatment of plaque psoriasis in adults. The FDA approved VTAMA for the topical treatment of mild, moderate, and severe plaque psoriasis in May 2022.
  - Dermavant is also developing VTAMA for the treatment of atopic dermatitis in adults and children and expects to release topline results from its Phase 3 clinical trials in the first half of calendar year 2023.
  - Dermavant's earlier stage development pipeline includes an additional novel aryl hydrocarbon receptor ("AhR") agonist, DMVT-506, with a similar profile to VTAMA. Dermavant is developing DMVT-506 for the treatment of immunological and inflammatory diseases.
- **Lead program:**
  - VTAMA is a novel, once daily, steroid-free topical cream approved in the US for the treatment of plaque psoriasis in adults. Dermavant is developing VTAMA for the treatment of atopic dermatitis in adults and children as young as age two.
  - VTAMA directly targets the AhR, a key regulator of skin homeostasis and inflammation.
- **Disease overview:**
  - Plaque psoriasis is a chronic, inflammatory disease of the skin characterized by lesions consisting of red patches and plaques with silvery scales.
  - Atopic dermatitis, the most common type of eczema, is a chronic condition characterized by dry, itchy skin.
  - Psoriasis and atopic dermatitis affect approximately 8 million and 26 million people in the United States, respectively.
- **Limitations of current treatment:**
  - Topical corticosteroids ("TCS") are the most common first-line therapies but they typically cannot be used for longer than four weeks due to the risk of significant side effects.
  - While oral and biologic therapies have become increasingly available, they are often limited to moderate-to-severe disease with often complicated access, reimbursement and utilization management requirements.
- **Clinical data:**
  - We completed two pivotal Phase 3 clinical trials, PSOARING 1 and PSOARING 2, for the use of VTAMA in treating mild, moderate, and severe plaque psoriasis in adults.
  - In both pivotal Phase 3 trials, which enrolled over 500 patients each, VTAMA met its primary endpoint and secondary endpoints with clinically meaningful and statistically significant results.
  - Our long-term open-label PSOARING 3 study provides supportive evidence of VTAMA's increased therapeutic effect beyond the 12-week double-blind treatment periods, suggesting treatment durability over time, as well as supportive evidence of a remittive effect, measured by time until disease worsening following treatment discontinuation.
- **Development plan and upcoming milestones:**
  - The FDA approved VTAMA for the once daily topical treatment of adults with plaque psoriasis in May 2022.

- VTAMA is the first topical novel chemical entity launched for plaque psoriasis in the U.S. in 25 years, offering a favorable mix of treatment effect, safety, tolerability, durability on therapy, and remittive effect.
- In September 2021, we dosed the first patient in our Phase 3 clinical trials of VTAMA for the treatment of atopic dermatitis, ADORING 1 and ADORING 2. We expect to report topline data from ADORING 1 and ADORING 2 in the first half of calendar year 2023.
- **Roivant ownership:**
  - As of March 31, 2022, we own 100% of the issued and outstanding common shares of Dermavant and 83% on a fully-diluted basis.

### **Commercial Launch of VTAMA for Treatment of Adults with Plaque Psoriasis**

The FDA approved VTAMA for the treatment of adults with mild, moderate or severe plaque psoriasis in May 2022.

Dermavant has built a highly specialized commercial sales organization focused on high value dermatology healthcare providers and their patients and implementing a “best-in-class” payor reimbursement and patient point of sale access strategy, which we believe ensures broad patient access at launch. As psoriasis patients are predominantly managed by dermatologists, we have deployed a team of approximately 100 specialty sales professionals focused on a core target base of top-decile dermatologists who write more than 80% of all commercial prescriptions in the psoriasis market. We believe a scientifically oriented, customer-focused team will allow us to reach the approximately 6,000 highest value dermatology healthcare providers.

For markets outside of the U.S., we may opportunistically seek strategic collaborations to maximize the commercial opportunities for VTAMA, if approved.

Since acquiring VTAMA in 2018, we have expanded our intellectual property portfolio with multiple patents, which are expected to provide intellectual property protection until 2038.

### **VTAMA for the Treatment of Psoriasis and Atopic Dermatitis**

VTAMA is a novel, once daily, cosmetically elegant, steroid-free topical cream. VTAMA directly targets the AhR, a key regulator of skin homeostasis and inflammation, to help reduce Th17 and Th2 cytokines, two pro-inflammatory pathways implicated in plaque psoriasis and atopic dermatitis, respectively, increase antioxidant activity, and promote skin barrier restoration. VTAMA cream is designed to be easy to apply, non-greasy and odorless, which we believe makes it cosmetically elegant. To date, over 2,200 subjects have been enrolled in 18 clinical trials of VTAMA and predecessor formulations of VTAMA cream.

#### *Psoriasis and atopic dermatitis*

Psoriasis and atopic dermatitis affect hundreds of millions of people globally each year, impacting their quality of life, including their physical health, psychological state, and overall well-being. While topical therapies are the foundation of treatment, many patients fail to achieve their desired outcome due to subpar efficacy, tolerability and safety concerns, application site restrictions and limits on duration of therapy.

Psoriasis is a chronic, inflammatory disease with skin lesions characterized by red patches and plaques with silvery scale that affects an estimated 8 million people in the United States. Its most common form, psoriasis vulgaris or plaque psoriasis, constitutes approximately 80 to 90% of all cases of psoriasis. Psoriasis severity is typically classified by body surface area (“BSA”) involvement: mild (less than 3% BSA), moderate (3% to 10% BSA) and severe (greater than 10% BSA). Based on this classification, approximately 80% of patients with psoriasis in the United States have mild to moderate disease, which is most often amenable to topical treatment.

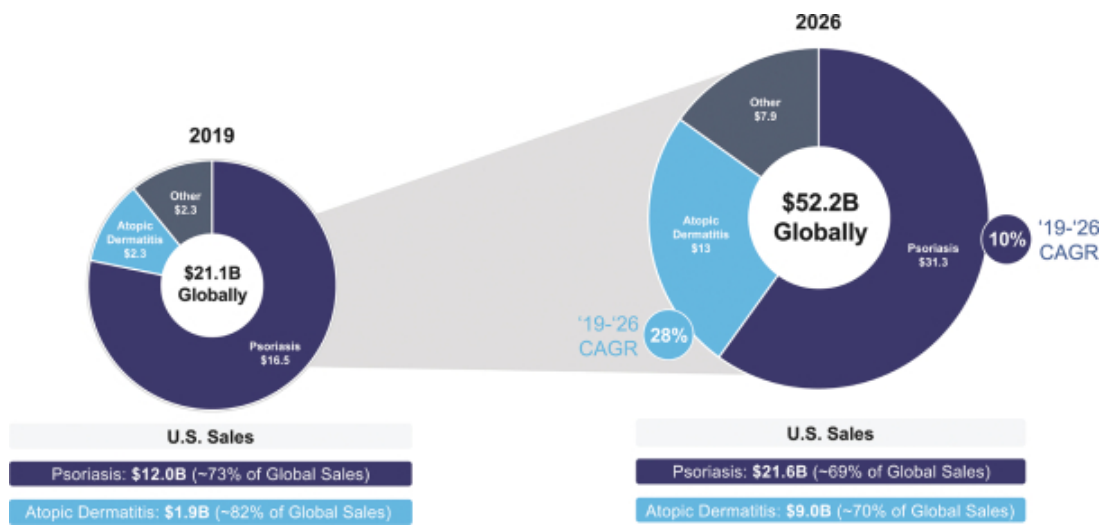
Atopic dermatitis is the most common type of eczema, affecting more than 9.6 million children and about 16.5 million adults in the United States. It is a chronic condition characterized by dry, itchy skin that often turns into a red rash. Atopic dermatitis can come and go for years or throughout life and can overlap with other types of eczema. Atopic dermatitis has a complex pathophysiology involving genetic, immunologic and environmental factors, culminating in skin barrier dysfunction and immune system dysregulation. The condition occurs most frequently in children (15 to 30% worldwide). Approximately 60% of those who develop atopic dermatitis show symptoms in the first year of life and up to 90% show symptoms by five years of age. While more prevalent in infancy and adolescence, one in ten people will develop atopic dermatitis. Approximately 89% of adult patients have mild to moderate atopic dermatitis, while 11% have severe atopic dermatitis.

TCSs are commonly used as the first-line therapy for the treatment of inflammatory skin conditions, such as psoriasis and atopic dermatitis. They are broadly available in generic form and carry FDA class labeling that restrict their duration of use, typically to no more than four weeks, and their location of use, prohibiting use in sensitive skin areas such as the face, groin, or axillae (armpit). While many people experience improvement with TCS, the continual long-term use of TCS has the potential to cause significant side effects including skin atrophy. As a result, healthcare professionals and patients are limited to intermittent treatment cycles of TCS therapy, leading to frequent disease flares and recurrence of disease, providing an inadequate solution for chronic conditions in immuno-dermatology. Topical calcineurin inhibitors (“TCI”) are an additional non-steroidal option for the topical treatment of atopic dermatitis, but their use is limited by safety concerns, including black box warnings of malignancy reported in patients treated with TCIs. Oral and biologic therapies have become increasingly available but are often limited to moderate-to-severe psoriasis and atopic dermatitis patients which comprise the smallest percentage of the affected populations. While biologics have proven to be very effective, their use has also been limited by concerns with systemic side effects, high cost, and reimbursement and access restrictions. Oral therapies are functionally limited to moderate-to-severe psoriasis patients. Oral therapies also have significant side effects and have not achieved the same level of efficacy as biologics. Additionally, recent FDA action regarding Janus kinase inhibitors (“JAKs”) have resulted in restrictive labeling and black box warnings relating to safety concerns with the product class, including oral and topical forms, and including for the topical treatment of atopic dermatitis.

Given the limitations associated with TCS, other topicals, orals, and biologics therapies, patients with inflammatory skin conditions often report dissatisfaction with their current treatment options. We see an opportunity for a novel, once daily topical treatment like VTAMA to fill the need for a long-term treatment option for plaque psoriasis and atopic dermatitis. Additionally, we believe that VTAMA has the potential to be used as a complementary therapy with biologics and oral therapies.

Psoriasis and atopic dermatitis represent the two largest markets in immuno-dermatology and are expected to reach total sales of approximately \$31 billion in the U.S. and \$44 billion globally by 2026. Topical treatments serve as the foundation of dermatologic treatment, representing 83% of all U.S. prescriptions written by dermatologists in 2020. Annual U.S. prescriptions for both psoriasis and atopic dermatitis are outlined below:

	<u>TCS</u>	<u>Vitamin D / Combos / Retinoids</u>	<u>Biologics</u>	<u>Otezla</u>	<u>Other Oral</u>
<b>Annual Scripts for PsO (2020)</b>	~2.35M	~508K	~1.05M	~258K	~241K
	<u>TCS</u>	<u>TCI</u>	<u>Eucriisa</u>	<u>Dupixent</u>	
<b>Annual Scripts for AD (2020)</b>	~16.4M	~996K	~352K	~344K	



Source: EvaluatePharma

## VTAMA for the Treatment of Psoriasis

### Clinical data

We completed two pivotal Phase 3 clinical trials, PSOARING 1 and PSOARING 2, evaluating the use of VTAMA in treating mild, moderate and severe plaque psoriasis in adults. In both of these trials, which enrolled over 500 patients each, VTAMA met its primary endpoint and all secondary endpoints with clinically meaningful and statistically significant results as well as favorable safety and tolerability findings. At week 12, 35.4% and 40.2% of patients treated with VTAMA in PSOARING 1 and PSOARING 2, respectively, achieved the primary efficacy endpoint of a Physician Global Assessment (PGA) score of clear (0) or almost clear (1) with a minimum 2-grade improvement from baseline as compared to 6.0% and 6.3% of patients treated with vehicle control cream ( $p < 0.0001$ ;  $p < 0.0001$ ). When this endpoint was evaluated over time, rapid onset of activity was observed with separation emerging by the first evaluation trial visit (week 2) and statistically significant differences between VTAMA and vehicle control cream at week 4 and continuing at all measured time points thereafter.

VTAMA met all secondary endpoints with statistical significance in PSOARING 1 and PSOARING 2, including a key secondary endpoint, the proportion of subjects with  $\geq 75\%$  improvement in Psoriasis Area and Severity Index (PASI75). In PSOARING 1 and 2, 36.1% and 47.6% of patients achieved PASI75 at Week 12 with VTAMA 1% cream QD vs 10.2% and 6.9% for vehicle control cream, respectively. Additionally, the proportion of patients with  $\geq 90\%$  improvement in Psoriasis Area and Severity Index (PASI90) at Week 12, also a secondary endpoint, was statistically significantly higher in both VTAMA groups compared with vehicle control cream ( $p = 0.0005$  and  $p < 0.0001$ ). In PSOARING 1 and PSOARING 2, 18.8% and 20.9% of patients treated with VTAMA, respectively, achieved PASI90 compared to 1.6% and 2.5%, respectively, of patients treated with vehicle control cream. The PASI assessment is a more quantitative assessment of disease activity relative to the PGA and provides additional insight into a drug's impact on disease modification. Similar to what was observed with PGA, evaluating reduction in the burden of disease via a PASI assessment confirms rapid onset of action with separation of VTAMA from vehicle control cream control at week 2, and statistically significant differences were noted as early as week 4 and each evaluation thereafter.

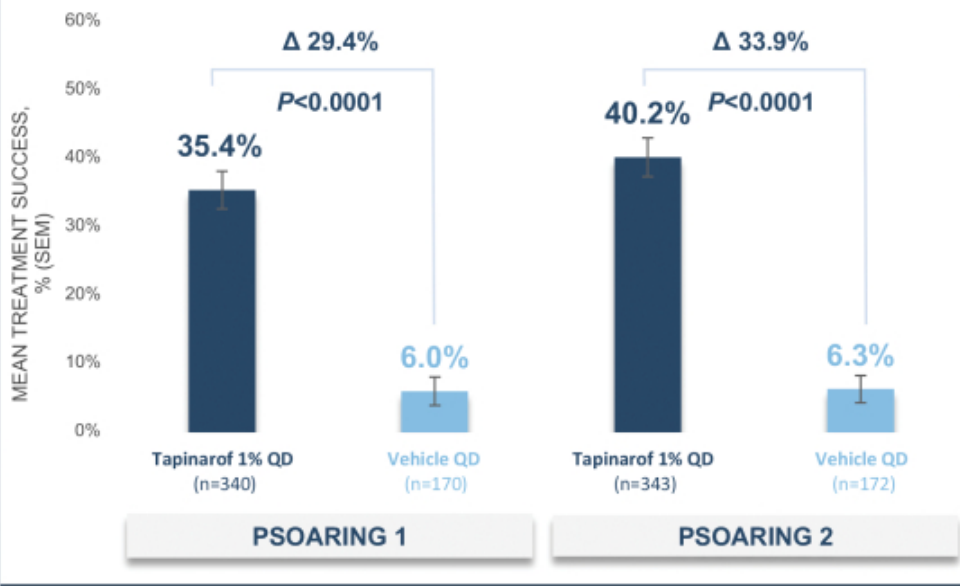
Additionally, VTAMA was observed to be well-tolerated, consistent with previous trials, and had low discontinuation rates due to adverse events ("AEs"), no treatment related serious adverse events ("SAEs"), and minimal severe application site reactions.

AEs were generally mild to moderate in nature with the majority consisting of localized skin reactions. Overall trial discontinuations due to adverse events were 5.6% in PSOARING 1 and 5.8% in PSOARING 2. Trial discontinuation rates due to folliculitis were 1.8% in PSOARING 1 and 0.9% in PSOARING 2. No VTAMA-related serious adverse events were observed, and over 90% of eligible patients enrolled in the open-label, long-term extension study. To date, over 2,200 subjects have been enrolled in 18 clinical trials of VTAMA and predecessor formulations of VTAMA cream.

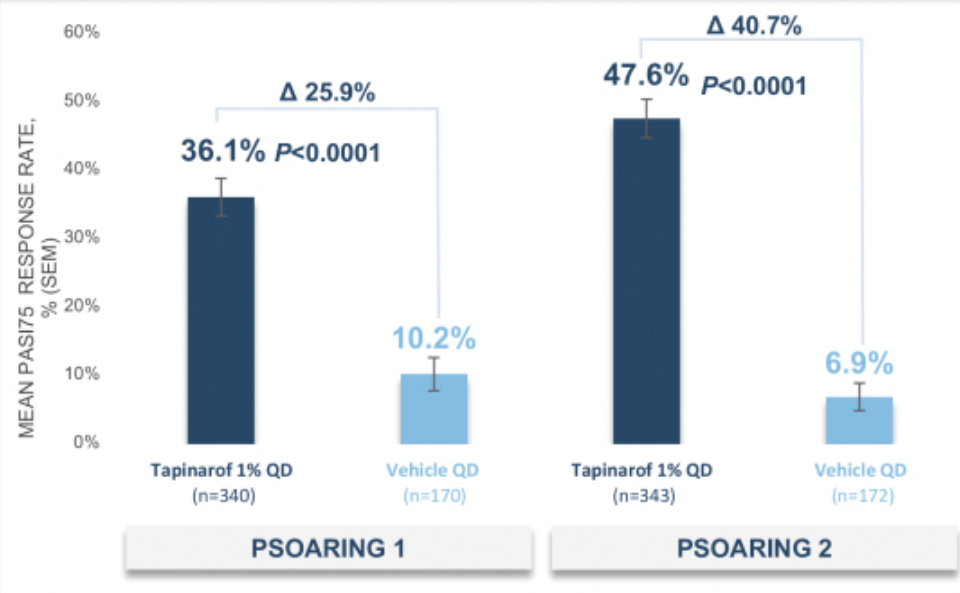


\* Patients with PGA of 2 (mild) and PGA of 4 (severe) limited to ~10% each of the total randomized population; ~80% of the total randomized population with PGA of 3 (moderate); †Patients electing not to participate in LTE had follow-up visit 4 weeks after completion of treatment period. BSA, body surface area; LTE, long-term extension; PASI75,  $\geq 75\%$  improvement in Psoriasis Area and Severity Index; PASI90,  $\geq 90\%$  improvement in Psoriasis Area and Severity Index; PGA, Physician Global Assessment; QD, once daily. 1. Clinicaltrials.gov; NCT03956355. 2. Clinicaltrials.gov; NCT03983980. 3. Clinicaltrials.gov; NCT04053387.

**PGA Score of 0 or 1 &  $\geq 2$ -grade Improvement from Baseline at Week 12 (ITT, MI)**

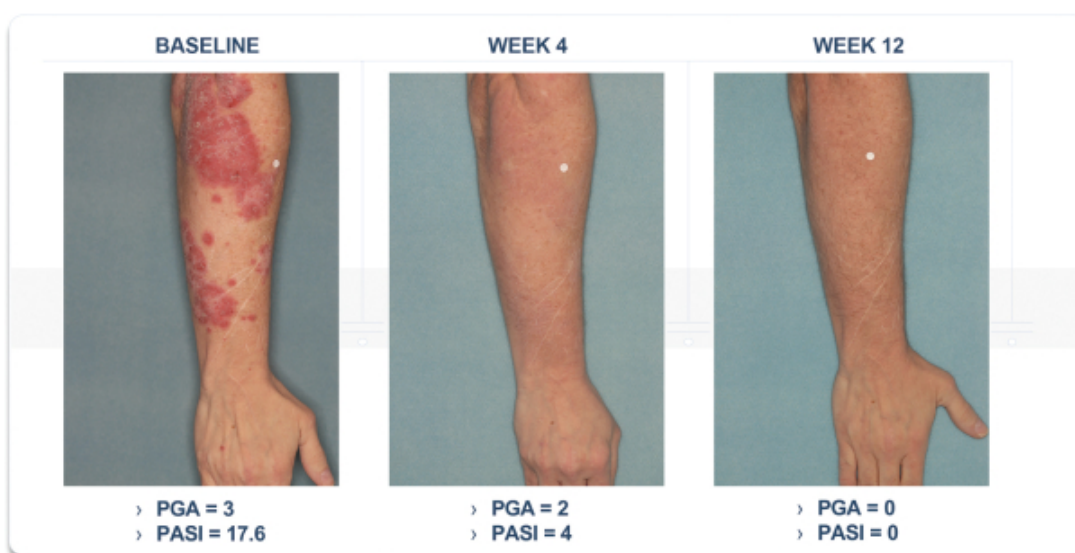


**PASI75 from Baseline at Week 12 (ITT, MI)**



Patients, n (%)	PSOARING 1		PSOARING 2	
	Tapinarof 1% QD (n=340)	Vehicle QD (n=170)	Tapinarof 1% QD (n=343)	Vehicle QD (n=172)
<b>TEAE</b>	171 (50.3)	38 (22.4)	187 (54.5)	45 (26.2)
Mild	76 (22.4)	16 (9.4)	80 (23.3)	17 (9.9)
Moderate	82 (24.1)	22 (12.9)	98 (28.6)	28 (16.3)
Severe	11 (3.2)	0 (0.0)	8 (2.3)	0 (0.0)
<b>Serious TEAE</b>	9 (2.6)	0 (0.0)	7 (2.0)	0 (0.0)
<b>Study discontinuation due to AEs</b>	19 (5.6)	0 (0.0)	20 (5.8)	1 (0.6)
<b>Most common treatment related TEAEs (≥1% in any group)</b>				
Folliculitis	70 (20.6)	2 (1.2)	54 (15.7)	1 (0.6)
Contact dermatitis	13 (3.8)	1 (0.6)	16 (4.7)	0 (0.0)
Headache	5 (1.5)	1 (0.6)	1 (0.3)	0 (0.0)
Pruritus	4 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)
Dermatitis	1 (0.3)	0 (0.0)	4 (1.2)	0 (0.0)
<b>Study discontinuation due to AESI</b>				
Folliculitis	6 (1.8)	0 (0.0)	3 (0.9)	0 (0.0)
Contact dermatitis	5 (1.5)	0 (0.0)	7 (2.0)	0 (0.0)
Headache	1 (0.3)	0 (0.0)	2 (0.6)	0 (0.0)
<b>Severity of folliculitis, n (%) among subset of patients with AESI of folliculitis</b>				
Mild	51 (63.8)	1 (50.0)	44 (72.1)	0 (0.0)
Moderate	28 (35.0)	1 (50.0)	17 (27.9)	1 (100.0)
Severe	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

The images below show rapid and complete clearance of plaque psoriasis in a patient achieving the defined trial endpoint. At baseline, this patient's PGA score was 3, indicative of moderate disease, and the PASI score was 17.6. The baseline image demonstrates classic plaque psoriasis with well-demarcated erythematous scaling plaques. At week 4, the PGA had decreased from 3 to 2 and the PASI from 17.6 to 4, the latter having passed the threshold 75% reduction in PASI (PASI75). The target plaques on the forearm completely resolved. At week 12, both the PGA and PASI scores were 0, indicating complete clearance of disease. PGA and PASI are global efficacy assessments.



In September 2021, we reported the final results from our long-term open-label study, PSOARING 3, which showed that 58.2% of subjects who entered the PSOARING 3 study with a PGA score of  $\geq 2$  achieved a PGA score of 0 or 1 at least once during the study. Although PSOARING 3 was not a vehicle-controlled study like the PSOARING 1 and PSOARING 2 studies, we believe these data provide supportive evidence regarding

VTAMA's potential therapeutic effect beyond the 12-week double-blind treatment periods utilized in the prior PSOARING studies. In addition, 312 out of 763 subjects (40.9%) achieved complete disease clearance (PGA score of 0) at least once during the study. We observed no evidence of tachyphylaxis, or a diminishing response to treatment, throughout the study, which we believe suggests treatment durability over time.

Relatedly, in our clinical trials, including data from our PSOARING 3 long-term open-label study, we have also observed that some patients treated with VTAMA maintained clinically meaningful disease control for an extended period of time after therapy had been discontinued. In PSOARING 3, subjects discontinued applying VTAMA when they achieved complete clearance of their disease (PGA=0). These subjects were then followed, and the time to first worsening (defined as PGA  $\geq$  2) was utilized to determine the maintenance of clinical benefit off therapy. We refer to maintenance of clear/almost clear (PGA 0/1) while off therapy as remittive effect. At the completion of the Week 12 visit of the PSOARING 1 and PSOARING 2 trials, subjects were offered enrollment in the PSOARING 3 long-term open-label study. Subjects with a PGA  $\geq$  1 began treatment with VTAMA cream applied QD until they achieved a PGA score of 0. Treatment was then discontinued and re-initiated when a patient's psoriasis subsequently worsened (PGA  $\geq$  2).

In PSOARING 3, for subjects entering the study with a PGA score of 0 (79/763), the median time to disease worsening (defined as a PGA score of  $\geq$  2) following complete disease clearance and treatment discontinuation was approximately 115 days. In addition, among patients entering PSOARING 3 with or achieving a PGA score of 0 (312/763), the mean total duration of time to disease worsening following treatment discontinuation was approximately 130 days. We believe these additional clinical observations confirm the long-term effectiveness of VTAMA cream 1% QD and differentiate it from other topical therapies.

## **VTAMA for the Treatment of Atopic Dermatitis**

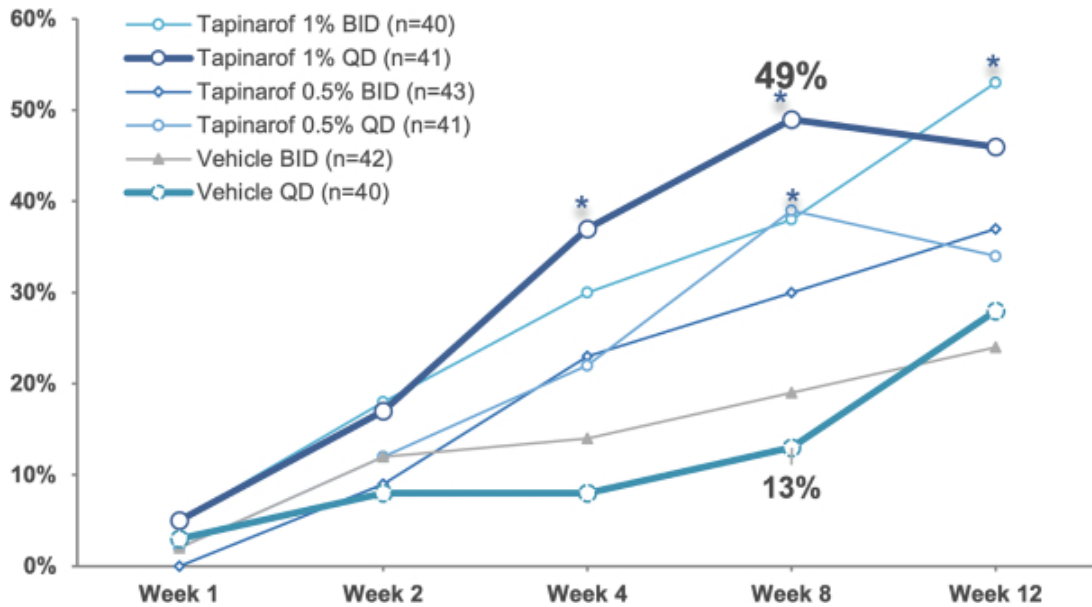
### *Clinical data*

In 2017, GSK completed a multi-center randomized, double-blind, vehicle cream-controlled Phase 2b clinical trial of VTAMA for the treatment of atopic dermatitis in 247 adult (aged 18 to 65 years) and adolescent (aged 12 to 17 years) patients. Patients were randomized equally to six treatment groups: VTAMA cream 0.5%, VTAMA cream 1% or vehicle cream, each applied to atopic dermatitis lesions either QD or BID. The primary endpoint was the percentage of patients who achieved a minimum two-point improvement in the Investigator Global Assessment ("IGA") score and an assessment of "clear" or "almost clear" skin at week 12. These cases were considered a "treatment success." Secondary endpoints included the percentage of patients with at least a 75% improvement in Eczema Area and Severity Index (EASI) from baseline. Efficacy was evaluated in the intent-to-treat ("ITT") population.

Overall, the percentage of patients achieving treatment success was much higher for both VTAMA concentrations than vehicle cream, with a robust dose response. 53% of patients who applied VTAMA cream 1% BID and 46% of those who applied it QD were considered a treatment success. This compares favorably to the 24% and 28% of patients who achieved a treatment success for the BID and QD vehicle cream groups, respectively. At week 12, 60% and 51% of patients treated with VTAMA cream 1% BID and QD, respectively, achieved EASI75. The treatment effect across adults and adolescents was observed to be consistent. Patient-reported outcome data was collected during the Phase 2b clinical trial, including data on reduction in the severity of pruritus. At week 12, more patients treated with VTAMA cream 1% (78% of patients treated BID and 87% of patients treated QD) reported "moderately improved" to "very improved" pruritus, compared to patients treated with vehicle cream (47% of patients treated BID and 64% of patients treated QD).



**IGA score 0 or 1 and  $\geq 2$ -grade improvement at Week 8**  
 Primary Endpoint was at 12 Weeks: Assessed in ITT Population (NRI Analysis)



IGA response: IGA score of 0 or 1 and a  $\geq 2$ -grade improvement from baseline.

\* Difference versus vehicle cream is statistically significant at  $p=0.05$  level (the 95% confidence interval excludes 0).

VTAMA was observed to be well-tolerated in this Phase 2b trial for atopic dermatitis, with the majority of AEs reported as mild or moderate in severity. In the trial, AEs were considered treatment-related (“TEAEs”) in 10% to 19% of patients across the treatment arms. The most commonly reported TEAEs were folliculitis, application-site pain and atopic dermatitis. TEAEs led to permanent discontinuation of treatment in 4% of dosed patients (seven patients from treatment groups total) compared to 7% of patients receiving vehicle cream (six patients total). Only one patient (tapinarof 1% BID) experienced a SAE of anxiety and hyperactive disorder, which was not considered to be related to treatment.

*Development plan*

In September 2021, we dosed our first patient in the ADORING 1 and ADORING 2 trials, two identically designed, multi-center, randomized, vehicle-controlled, double-blind parallel Phase 3 clinical trials of VTAMA for the treatment of atopic dermatitis. We expect to release topline data from these studies in the first half of calendar year 2023. The two trials will enroll up to 800 patients across both trials to evaluate the safety and efficacy of VTAMA cream, 1% dosed once daily for 8 weeks versus vehicle cream QD in patients aged two years and older who have moderate to severe atopic dermatitis. The primary endpoint of both studies will be the percentage of patients achieving a Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™), of 0 or 1 with at least a 2-grade improvement from baseline at week 8.

Additionally, we have initiated ADORING 3, a long-term, open-label, extension study to evaluate the safety and efficacy of VTAMA cream 1% in patients with atopic dermatitis. Subjects in the study will include those who have previously completed treatment with VTAMA or vehicle in ADORING 1 or ADORING 2, as well as

subjects who have completed a maximal use PK study, and those pediatric subjects who would not qualify for inclusion in ADORING 1 or 2 due to milder or more severe disease. ADORING 3 will consist of up to 48 weeks of VTAMA cream 1%, and a 7-day safety follow-up period.

### Potential Benefits of VTAMA—Limitations of Current Treatments

#### *VTAMA in plaque psoriasis*

We believe VTAMA has several key attributes that position it favorably over current standard of care treatments in plaque psoriasis, including TCS therapies:

The infographic consists of three dark blue rounded rectangular boxes stacked vertically. Each box contains an icon on the left and text on the right. The first box features a purple icon of a scale with '6x' below it, followed by the heading 'POWERFUL EFFICACY' and the text '6x the efficacy vs vehicle in 12-week pivotal studies (36% and 40% PGA success rate achieved in the VTAMA cream arm vs 6% in vehicle arm)'. The second box features a purple icon of a calendar with '~4' and 'MONTHS' below it, followed by the heading 'RESULTS THAT LAST' and the text 'Durable ON-treatment results with no tachyphylaxis for up to 52 weeks & Lasting Remittive OFF-treatment effect seen for median of ~4 months'. The third box features a purple icon of a thumbs-up hand, followed by the heading 'SAFE & WELL-TOLERATED' and the text 'Versatility to be used in mild, moderate & severe psoriasis on all affected skin areas (including sensitive skin), no restrictions on duration of use & no label safety warnings or precautions'.

Based on the clinically meaningful and statistically significant reduction in psoriasis symptoms VTAMA demonstrated in both Phase 3 trials, coupled with no label restrictions on duration of use and no label safety warnings or precautions, we believe VTAMA will be used broadly and potentially chronically on any skin lesion regardless of location on the body. We believe the Phase 3 data we have generated and the data observed in our open-label, long-term extension study support the chronic use of VTAMA, potentially in place of other topical and oral treatments, for the treatment of mild, moderate and severe plaque psoriasis in adults.

#### *VTAMA's potential in atopic dermatitis*

TCS, especially low-to-mid potency TCS, represent the standard-of-care for atopic dermatitis treatment. Although they are used commonly, TCS pose a specific concern in pediatric patients due to the risk of systemic absorption, hypothalamic-pituitary-adrenal axis suppression, skin thinning and other potential side effects. The increased body surface area to mass ratio in children results in increased absorption and systemic exposure. The American Academy of Dermatology guidelines suggest limiting long-term use of TCS in children to avoid the risk of systemic side effects. As such, 86% of U.S. patients report dissatisfaction with current treatment options for atopic dermatitis according to the National Eczema Association. There is also considerable concern among many parents about treating their children with steroids, which can be an obstacle to treatment for physicians. Due to these risks and patient dissatisfaction, health care providers are less likely to use them long-term in children and also in sensitive skin areas such as the face or diaper/groin area. In addition, topical PDE4 inhibitors

developed to treat atopic dermatitis have been associated with side effects including application site burning and stinging. Topical calcineurin inhibitors are an additional non-steroidal option for the topical treatment of atopic dermatitis; however, their use has been limited by safety including boxed warnings of malignancy (e.g., skin and lymphoma) having been reported in patients treated with topical calcineurin inhibitors.

Patients whose disease flares despite topical treatments may be prescribed systemic agents such as oral corticosteroids or oral cyclosporine to rapidly relieve severe signs and symptoms of the disease. While these are effective as temporary treatments of flare-ups, extended use has been associated with many potential side effects or adverse events. Systemic steroids, such as prednisone, can lead to symptom relief, but their use is not recommended to induce stable remission due to numerous side effects associated with steroids and the propensity of severe disease flares upon abrupt treatment cessation. Cyclosporine is also generally not recommended for use lasting longer than one to two years, as it has been associated with renal toxicity, hirsutism, nausea and lymphoma. Based on data from the 2014 Adelphi U.S. AD Disease Specific Program, over 58% of adults with moderate-to-severe atopic dermatitis have disease which physicians consider to be inadequately controlled by these therapeutic modalities. While biologic therapies are more efficacious, as is the case in psoriasis, use of therapies such as the recently approved Dupixent is limited to patients with significant disease burden as they are expensive, necessitate frequent injections, entail regular physician appointments, have potential systemic toxicities and often require laboratory monitoring. Additionally, recent FDA action regarding JAK inhibitors has resulted in restrictive labeling and black box warnings relating to safety concerns with the product class, both oral and topical forms, including for the topical treatment of atopic dermatitis.

We believe VTAMA has the potential to fill the need for a long-term treatment option for atopic dermatitis. We also believe that VTAMA has the potential to offer significant clinical advancement to address the incessant flare cycle experienced by atopic dermatitis patients that is the result of the short-term use limitation of standard-of-care TCS.

#### *VTAMA sales and marketing potential in atopic dermatitis*

If VTAMA is approved by the FDA for the treatment of atopic dermatitis, we plan to expand our psoriasis sales team to be able to reach additional specialists who see a significant amount of atopic dermatitis patients, such as pediatric dermatologists and allergists. Based on our commercial team's experience developing and launching dermatology products in U.S., we believe we can effectively reach the psoriasis and atopic dermatitis core target base with a highly specialized sales team of 125 to 150 total sales representatives.

#### *DMVT-506 for Immunology and Inflammatory Diseases*

DMVT-506 is an early stage drug candidate that is a novel AhR agonist with a similar activity profile to VTAMA. We are evaluating DMVT-506 as a potential differentiated treatment option for immunology and inflammatory diseases. DMVT-506 is a unique, new chemical entity protected by a composition of matter patent having a natural expiration date in 2041.

## Immunovant Overview

- **Overview:**

- Immunovant is developing batoclimab for the treatment of Myasthenia Gravis (“MG”), Thyroid Eye Disease (“TED”) and Warm Autoimmune Hemolytic Anemia (“WAIHA”).

- **Lead program:**

- Batoclimab is a novel, fully human monoclonal antibody targeting the neonatal fragment crystallizable receptor (“FcRn”).
- Designed to be optimized as a simple, self-administered subcutaneous (“SC”) injection with dosing that we believe can be tailored based on disease severity and stage.
- In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce immunoglobulin G (“IgG”) antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in related disease areas.

- **Disease overview:**

- MG is an autoimmune disorder associated with muscle weakness and fatigue. The estimated prevalence of MG is 17.8 per 100,000, with up to 59,000 people in the U.S., and 24.2 per 100,000, or approximately 126,000 cases in Europe.
- TED is an autoimmune inflammatory disorder that affects the muscles and tissues surrounding the eyes, and in severe cases can be sight-threatening. TED has an estimated annual incidence of 9.7 in 100,000 in the U.S. and 4.8 in 100,000 Europe.
- WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells (“RBCs”), affecting approximately 40,000 patients in the U.S. and 71,000 patients in Europe.

- **Limitations of current treatments:**

- Early-stage disease: corticosteroids and immunosuppressants.
- Later-stage disease: intravenous immunoglobulin (“IVIg”), or plasma exchange.
- Approaches are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

- **Clinical data:**

- In the highest dose cohorts in the Phase 1 clinical trial, four weekly SC administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, with a standard deviation of 2%. Injection site reactions were similar between batoclimab and placebo arms.
- As previously disclosed, we voluntarily paused dosing in our early phase clinical studies to evaluate batoclimab-induced elevations in total cholesterol and low density lipoprotein (“LDL”) levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory agencies, we are continuing the clinical development of batoclimab.
- In 2019, we initiated an open-label, single-arm Phase 2a clinical trial of batoclimab for the treatment of TED. The majority of subjects (four of seven) evaluated at the end of treatment experienced a greater than or equal to 2-point improvement in clinical activity score (CAS) and three of seven subjects were proptosis responders, defined as a greater than or equal to 2mm reduction in proptosis in the study eye. In 2019, we initiated a randomized, masked, placebo-controlled Phase 2b clinical trial of batoclimab in TED. Our voluntary pause in dosing in February 2021 resulted in unblinding this trial and the primary

endpoint was not significant. However, our analysis of exploratory endpoints from this trial increased our confidence in the anti-FcRn mechanism of action for patients with TED, and they provide part of the basis for our interest in moving forward with further development of in this indication.

- In 2019, we initiated a multi-center, randomized, blinded, placebo-controlled Phase 2a clinical trial of batoclimab for the treatment of MG. As evaluated in a pre-specified, pooled analysis of 15 subjects who completed Day 42 of the trial, batoclimab-treated subjects (N=10) showed a clinical improvement in both the MG-ADL scale and the MGC scale.
- **Development plan and upcoming milestones:**
  - As previously disclosed in December 2021, we achieved alignment with the FDA Division of Neurology 1 to move forward with our pivotal trial of batoclimab as a treatment for MG. We have initiated our Phase 3 study in MG which is now open for enrollment. We expect top-line data from this Phase 3 trial to be available in the second half of calendar year 2024.
  - We plan to initiate two Phase 3 clinical trials to evaluate batoclimab for the treatment of TED in the second half of calendar year 2022, and we expect top-line results from both Phase 3 trials to be available in the first half of calendar year 2025.
  - We plan to announce two new indications by August 2022, and we expect one of the three indications, including WAIHA, to be initiated as a pivotal trial in calendar year 2022.
- **Roivant ownership:**
  - As of March 31, 2022 we own 63% of the issued and outstanding shares of Immunovant common stock and 58% on a fully diluted basis.

## **Batoclimab**

Batoclimab is a novel, fully human monoclonal antibody that selectively binds to and inhibits FcRn. In nonclinical studies and in clinical trials conducted to date, batoclimab has been observed to reduce IgG antibody levels. High levels of pathogenic IgG antibodies drive a variety of autoimmune diseases and, as a result, we believe batoclimab has the potential for broad application in these disease areas.

In addition to generating clinically meaningful IgG reductions, batoclimab has been designed from inception to be a fixed-dose, self-administered SC injection on a convenient weekly, or less frequent, dosing schedule. Batoclimab has been dosed in small volumes (e.g., 2 mL) and with a 27-gauge needle, while still generating therapeutically relevant pharmacodynamic activity, important attributes that we believe will drive patient preference and market adoption. We believe that batoclimab, if developed and approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases. The patent family directed to the composition of matter of batoclimab has a natural projected expiration date in 2035 in the U.S. and in foreign jurisdictions.

In several nonclinical studies and in a multi-part Phase 1 clinical trial in healthy volunteers, intravenous and SC delivery of batoclimab was generally well tolerated and demonstrated dose-dependent IgG antibody reductions. In the highest dose cohorts in the Phase 1 clinical trial, four weekly SC administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, with a standard deviation of 2%. Injection site reactions were similar between batoclimab and placebo arms.

### *Mechanism of action*

The neonatal fragment crystallizable receptor, or FcRn plays a pivotal role in preventing the degradation of IgG antibodies. The physiologic function of FcRn is to modulate the catabolism of IgG antibodies. FcRn intercepts IgG, which would otherwise be degraded in lysosomes. The FcRn-IgG complex is then recycled to the

cell surface and free IgG is released back into circulation. Anti-FcRn antibodies bind to FcRn, thereby preventing it from recycling IgG antibodies back to circulation. As a result, IgG is increasingly delivered to lysosomes for degradation. The inhibition of FcRn, such as through use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies, suggesting utility in the many autoimmune diseases associated with high levels of such IgG antibodies.

## **Batoclimab for the Treatment of MG**

### *MG overview*

MG is an autoimmune disorder associated with muscle weakness and fatigue. MG patients develop antibodies 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. This leads to muscle weakness intensified by activity, which can be localized exclusively to ocular muscles or which can be more generalized throughout the body including muscles of respiration. Patients with localized ocular disease suffer from more limited symptoms, including droopy eyelids and blurred or double vision due to compromise of eye movements. The vast majority of MG patients demonstrate elevated serum levels of acetylcholine receptor (“AChR”) antibodies which disrupt signal transmission between nerve fibers and muscle fibers. These antibodies ultimately lead to fluctuating muscle weakness and fatigue.

The prevalence of MG is estimated to be 17.8 per 100,000, with up to 59,000 cases in the U.S. Third-party studies estimate the prevalence in Europe for MG as 24.2 per 100,000, or approximately 126,000 cases. MG can occur at any age; however, the age of onset tends to follow a bimodal distribution. Early onset disease usually occurs in individuals between 10 to 30 years old and predominantly affects females. Later onset disease usually occurs in individuals over 50 years old and predominantly affects males. As with many autoimmune diseases, there are no known genetic alterations that specifically cause MG, and in most patients, it arises spontaneously. Approximately 3% of patients have a primary relative with MG, suggesting that there are genetic factors that may predispose development of the disease, but these genes have yet to be identified.

The symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months or remain chronic. After 15 to 20 years, some weakness often becomes fixed, with the most severely affected muscles frequently becoming atrophic. Many patients find it difficult to perform daily activities due to both insufficient improvement in symptoms even after treatment and in some the complicating long-term side effects of oral corticosteroids, a common treatment for MG. Approximately 15% to 20% of MG patients will experience at least one myasthenic crisis over their lifetimes. During myasthenic crisis, the impairment of muscles required to breathe can become life-threatening, leading to death in approximately 2% to 5% of cases. Up to 90% of patients in myasthenic crisis require intubation and mechanical ventilation leading to hospital stays lasting a median of 17 days. Over half of the patients who survive such a crisis remain functionally dependent upon discharge from the hospital.

Very early stage MG is symptomatically treated with acetylcholinesterase inhibitors such as pyridostigmine. As the disease progresses, patients are typically treated with immunosuppressive agents such as glucocorticoids, azathioprine, mycophenolate mofetil and cyclosporine. Thymectomy may be indicated for treatment in patients with evidence of a thymoma and can be considered for treatment in some younger patients who do not have evidence of thymoma. As MG becomes more advanced, patients can be treated during exacerbations with IVIg, which provides therapeutic benefit through multiple potential mechanisms including the saturation of FcRn. Physicians direct patients with more advanced chronic disease and patients in times of crisis to therapies that reduce levels of circulating IgG antibodies via plasma exchange or a variant of this plasma exchange, immunoadsorption. The most recent agents approved for MG are eculizumab and ravulizumab-cwvz, two complement C5 inhibitors, the use of which are limited to patients refractory to available therapy with anti-AChR-positive MG. Efgartigimod, an anti-FcRn antibody fragment, was recently approved for the treatment of MG in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. We believe there is room to

improve upon this current treatment paradigm for MG, as some of these treatments can leave patients with burdensome administration requirements, significant side effects or long wait times to see treatment effect.

### Clinical data

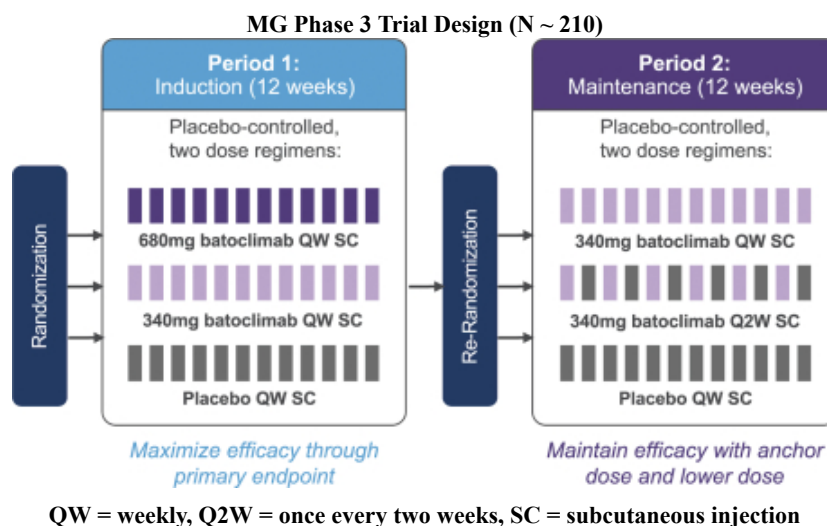
In 2019, we initiated a multi-center, randomized, blinded, placebo-controlled Phase 2a clinical trial of batoclimab for the treatment of MG. As evaluated in a pre-specified, pooled analysis of 15 subjects who completed Day 42 of the trial, batoclimab-treated subjects (N=10) showed a clinical improvement in both the MG-ADL scale and the MGC scale. We believe, based upon our review of data from this Phase 2a trial of batoclimab in MG, that there is sufficient proof of concept to pursue a pivotal trial to evaluate batoclimab for the treatment of MG.

### Development plan

As previously disclosed in December 2021, we achieved alignment with the FDA Division of Neurology 1 to move forward with our pivotal trial of batoclimab as a treatment for MG. We have initiated our Phase 3 study in MG which is now open for enrollment. We expect top-line data from this Phase 3 trial to be available in the second half of calendar year 2024.

Our trial is designed to address unmet patient needs and differentiate batoclimab from other treatments. Key features of the trial include:

- 12-week Induction Period: Includes doses of 680 mg SC injection weekly (“SC QW”) or anchor dose of 340 mg SC QW compared to placebo. The objective is to achieve maximum efficacy at the beginning of treatment and determine the potential benefit of 680 mg SC QW (i.e., speed and depth of clinical response).
- 12-week Maintenance Period: Includes anchor doses of 340 mg SC QW and 340 mg SC injection once every two weeks compared to placebo to assess lower effective maintenance doses with potentially fewer side effects related to long term IgG suppression or serum analyte changes.
- 52-week Long Term Extension: Includes long term safety assessment of the 2 maintenance doses; also includes tailored dosing allowing for treatment of disease exacerbations with short-term, re-induction dosing of batoclimab (680 mg SC QW x 4 weeks) followed by resumption of 340 mg SC QW.



### *TED overview*

TED, also referred to as Graves' Ophthalmopathy or GO, is a sight-threatening autoimmune inflammatory disorder that affects the muscles and tissues surrounding the eyes. Initial symptoms may include a dry and gritty ocular sensation, sensitivity to light, excessive tearing, double vision, and a sensation of pressure behind the eyes. At diagnosis, many patients with TED have retraction of their upper eyelids, swelling and redness surrounding the eyes, and protrusion of their eyeballs (proptosis). In some cases, swelling and stiffness of the eye muscles prevent the eyes from working together causing double vision. Approximately 3% to 5% of TED patients have a severe manifestation of the disease causing intense pain, inflammation, sight-threatening corneal ulcers, or optic neuropathy requiring surgical intervention. Decompression surgery to improve ocular function or rehabilitative surgery to improve quality of life is required in up to 20% of TED patients.

TED is most commonly caused by IgG autoantibodies that form against the thyroid-stimulating hormone receptor ("TSHR"). These anti-TSHR antibodies activate cells in the extraocular space that highly express TSHR, such as fibroblasts and adipocytes. Fibroblast activation causes cell proliferation and the production of hyaluronan, a substance that contributes directly to the swelling associated with TED. Hyaluronan also serves as an inflammatory signal leading to the synthesis of cytokines that cause recruitment of lymphocytes leading to extensive tissue inflammation and remodeling. Adipocyte activation leads to hyperplasia of the adipose tissue surrounding the eye causing protrusion of the eyeballs and compression of the optic nerve. Levels of anti-TSHR autoantibodies correlate positively with clinical features of TED and influence its prognosis. Exposure to other inflammatory agents, such as cigarette smoke, leads to exacerbation of the disease resulting in more severe symptoms.

In addition to anti-TSHR autoantibodies, antibodies that activate the insulin-like growth factor 1 receptor ("IGF1R") may also contribute to TED. TSHR and IGF1R have functional overlaps and stimulation of either receptor may lead to activation of similar biochemical pathways implicated in TED. Published studies investing this pathway have led to the discovery that the IGF1R and TSHR form a receptor complex where IGF1R can augment the signaling of TSHR. The exact nature of the interaction between IGF1R and TSHR continues to be investigated; however, experimental evidence suggests that the effects of TSHR stimulating antibodies are only partially blocked by an IGF1R antagonist while they may be completely blocked with a TSHR antagonist.

TED has an estimated annual incidence of 9.7 in 100,000 in the U.S. and 4.8 in 100,000 in Europe. The natural history of TED begins with an inflammatory phase lasting between six and 24 months that is characterized by lymphocyte infiltration, fibroblast proliferation and increases in adipose tissue. The first line of treatment for TED patients is generally immunosuppressive therapy, including high doses of corticosteroids. Treatment of patients with immunosuppressive therapies during this active inflammatory phase can lead to reduction in symptoms and can alter the course of the disease. However, once the initial inflammatory phase is over, immunosuppressive therapies are ineffective and levels of fibrosis that have developed as the result of acute inflammation are only reversible by surgery. We estimate that 15,000 to 20,000 patients in the United States have active inflammatory TED each year and are eligible for treatment with therapy directed at the causative anti-TSHR antibodies.

As a first option, patients with active TED are treated with immunosuppressive therapy such as high doses of corticosteroids, typically administered intravenously or orally. Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse. This therapy is associated with an increased risk of acute and severe organ damage, bone thinning, weight gain, diabetes, hypertension, osteoporosis and depression. In January 2020, the FDA approved Horizon Therapeutics' Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED.

Orbital radiation therapy is used as a means of reducing the infiltration of lymphocytes and can be used in conjunction with corticosteroids or immunosuppressive therapy. Similar to these anti-inflammatory and immunosuppressive drugs, radiation therapy is most effective in the active stage of TED.



Patients with moderate-to-severe active TED not responding to corticosteroids can be treated with cyclosporine or mycophenolate mofetil, two broad immunosuppressive drugs. These drugs are associated with numerous side effects related both to their general immunosuppressive effects as well as to inherent toxicities, such as hypertension, kidney disease and gastrointestinal toxicity.

Small case studies have identified rituximab as an alternate way of inducing immunosuppression in patients with TED. Rituximab (Roche) is a monoclonal antibody that binds to an antigen specific to B cells, leading to their destruction. However, rituximab is associated with the potential for serious side effects, such as infusion-related reactions. Rare cases of progressive multifocal encephalopathy and other viral infections have also been reported.

Surgery is considered to be a treatment option in patients with a highly active disease who have been treated with corticosteroids or immunosuppressive therapy but continue to have progressive disease. The goal of surgery is to reduce the pressure causing proptosis, reduced eye movement and loss of visual acuity. Because of its invasive nature, surgery is typically reserved for inactive disease.

#### *Clinical data*

In 2019, we initiated an open-label, single-arm Phase 2a clinical trial of batoclimab for the treatment of TED. The majority of subjects (four of seven) evaluated at the end of treatment experienced a greater than or equal to 2-point improvement in clinical activity score (CAS). Three of seven subjects were proptosis responders; a proptosis response was defined as a greater than or equal to 2mm improvement in the study eye.

In 2019, we initiated a randomized, masked, placebo-controlled Phase 2b clinical trial of batoclimab in TED. Our voluntary pause in dosing in February 2021 resulted in unblinding this trial and the primary endpoint was not significant. However, our analysis of exploratory endpoints from this trial increased our confidence in the anti-FcRn mechanism of action for patients with TED, and they provide part of the basis for our interest in moving forward with further development of TED.

#### *Development plan*

We recently achieved alignment with the FDA Division of Ophthalmology to move forward in TED. We plan to initiate two Phase 3 clinical trials to evaluate batoclimab for the treatment of TED in the second half of calendar year 2022. For each of the two Phase 3 trials of batoclimab in TED, we expect that approximately 100 subjects will enter the trial and be randomized to either a treatment arm or placebo arm. Subjects randomized to the treatment arm will be dosed with 680 mg of batoclimab QW for 12 weeks followed by 340 mg of batoclimab QW for 12 weeks. This batoclimab-treated group of subjects will be compared to subjects that are dosed with placebo QW for 24 weeks. This treatment period will last for 24 weeks and the primary efficacy endpoint will be measured as proptosis responders at Week 24 vs placebo where responders are defined as  $\geq 2$  mm reduction from baseline in proptosis in the study eye without deterioration of  $\geq 2$  mm increase in the fellow eye. We expect top-line results from both Phase 3 trials to be available in the first half of calendar year 2025.

### **Batoclimab for the Treatment of WAIHA**

#### *WAIHA overview*

WAIHA is a rare hematologic disease in which autoantibodies mediate hemolysis, or the destruction of red blood cells (“RBCs”). The clinical presentation is variable and most commonly includes non-specific symptoms of anemia such as fatigue, weakness, skin paleness and shortness of breath. Symptoms typically develop chronically over several weeks to months; however rapid progression over a span of days has also been observed.

In severe cases, hemoglobin levels are unable to meet the body’s oxygen demand, which can lead to heart attacks, heart failure and even death. Though the exact causes of WAIHA are unknown, roughly half of cases occur in patients with an underlying lymphoproliferative or autoimmune disease, most commonly chronic lymphocytic leukemia, rheumatoid arthritis, or systemic lupus erythematosus.

In WAIHA, autoantibodies react with surface proteins on RBCs at temperatures at or above 37° Celsius, or normal body temperature. These antibodies are of the IgG subtype in most patients. WAIHA is differentiated from cold autoimmune hemolytic anemia, or cold agglutinin disease, which shares a similar clinical presentation but is triggered by autoantibodies that react at temperatures below 37° Celsius. In WAIHA, antibody-coated RBCs are removed from circulation primarily in the spleen, where they are destroyed by macrophages. Studies have suggested the severity of WAIHA correlates with the amount and potency of autoantibodies present.

The annual incidence of WAIHA in the United States and Europe is estimated at one to three in 100,000 persons. Based on published estimates, we believe that there are approximately 40,000 patients in the U.S. and 71,000 patients in Europe living with WAIHA. The disease may be more common in females, with some sources suggesting a 2:1 female predominance. Peak incidence occurs during the sixth and seventh decades of life, however, WAIHA can occur in children as well.

High doses of corticosteroids (>1 mg/kg of prednisone) are typically the first-line treatment option for WAIHA and lead to initial disease control in approximately 70-85% of cases. Once initial disease control is achieved, doses of steroids are tapered. However, only 33% of patients maintain sustained disease control once steroids are discontinued and, as a result, the majority of patients will require either long-term steroid treatment or additional therapies.

Patients with persistent disease despite use of corticosteroids and rituximab may be offered a course of other immunosuppressive drugs, such as cyclophosphamide, mycophenolate mofetil or azathioprine sirolimus.

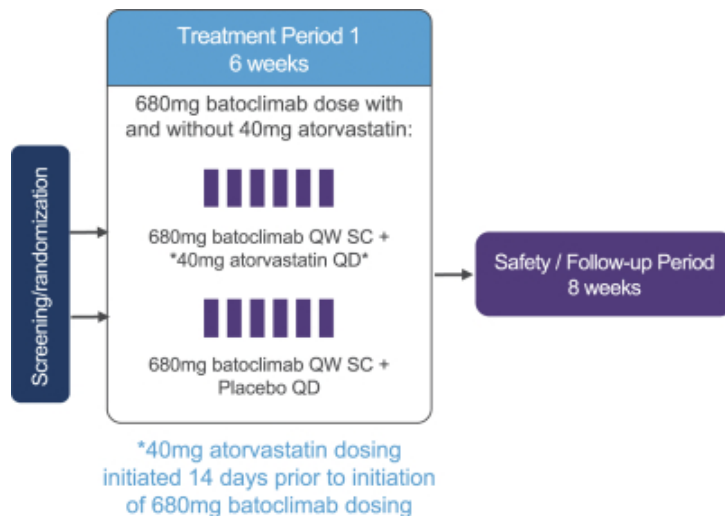
RBC transfusions are indicated in patients who require immediate stabilization. Such patients are monitored closely for evidence of a transfusion reaction. In contrast to other treatment modalities that lead to nonspecific suppression of the immune system, batoclimab may offer a more targeted approach for reducing levels of the causative IgG species responsible for most cases of WAIHA. We believe this could provide a favorable therapeutic window and avoid the significant side effects associated with less targeted immunosuppression.

#### *Development plan*

Following expected discussions with the hematology division of the FDA, we intend to initiate a randomized, placebo-controlled study of batoclimab as a treatment for WAIHA.

## Batoclimab and Atorvastatin drug-drug interaction (“DDI”) trial

In March 2022, we announced that we initiated a Phase 1 DDI study in healthy volunteers to characterize the PK profile of atorvastatin (40 mg daily (“q day”) with and without the coadministration of batoclimab 680 mg SC QW (see figure below). Key secondary objectives are to compare the change from baseline in lipid levels observed with SC QW batoclimab (680 mg or 340 mg SC) alone or in combination with varying doses of atorvastatin. Preliminary results from the initial 2 cohorts dosed in the study (680 mg SC QW with and without 40 mg atorvastatin q day) suggest that, at these doses, atorvastatin negates the batoclimab-induced increase in LDL-cholesterol. We believe, based on these preliminary data and feedback from physicians, that a batoclimab-induced increase in LDL-cholesterol can be managed with anti-lipid therapy as needed. Results from the additional cohorts studied are expected to be available by the end of calendar year 2022.



QW = weekly, QD = daily, SC = subcutaneous injection

### Potential New Indications

We continue to evaluate potential new indications for batoclimab by considering a number of factors including, but not limited to, degree of unmet medical need, potential benefit offered by the treatment, target patient population size, and commercial potential.

We have identified additional attractive indications with high unmet need and scientific rationale for anti-FcRn therapy. We also believe that certain indications with existing anti-FcRn programs offer a significant opportunity to provide unique patient benefits and therefore represent a strong potential opportunity. As previously disclosed, we plan to announce two new indications by August 2022.

## Proteovant Overview

- **Overview:**

- Proteovant is focused on the discovery and development of a robust pipeline of protein degraders targeting indications in oncology and immunology.

- **Protein degradation:**

- Protein degraders are a novel class of small molecules that target and destroy cellular proteins, rather than inhibiting them. Degraders are engineered to induce the degradation of specific disease-causing proteins through the ubiquitin-proteasome system, which ordinarily tags and degrades proteins that have been misfolded or have already fulfilled their biological function.
- In heterobifunctional degraders, the protein ligand domain, commonly referred to as a “warhead,” targets the specific protein of interest. At the other end of the complex, the ligase ligand recruits a specific E3 ubiquitin ligase. Both ends of the complex are connected by a linker that orients the target protein and E3 ligase in a cooperative ternary complex, driving ubiquitination. Similar to heterobifunctional degraders, molecular-glue-type degraders are small molecules that induce a novel interaction between a ligand of an E3 ubiquitin ligase and a target protein, leading to proteolysis of the target via the ubiquitin-proteasome system.
- We believe degraders represent a promising new approach to drug previously “undruggable” targets and transform the treatment of diseases with significant unmet medical need. Degraders open a new set of opportunities for small molecule drug development and have multiple distinct potential advantages over inhibitors, including that they:
  - are not bound by “inhibitory” requirements, meaning they can target historically “undruggable” proteins, including transcription factors and scaffolding proteins that lack a catalytic pocket;
  - may achieve efficacy at lower doses to decrease off-target dose-limiting toxicities; and
  - have demonstrated protein depletion in tumors that have shown resistance to specific inhibitors.

- **Proteovant’s degrader strategy:**

Proteovant is positioned for leadership in the field of targeted protein degradation given its long-term sponsored research agreement (“SRA”) with a leading academic lab, its internal R&D capabilities, as well as degrader-specific machine learning capabilities.

- Proteovant is leveraging leading protein degrader capabilities via its SRA with the lab of Dr. Shaomeng Wang, a world-renowned scientist focused on the discovery of protein degraders, at the University of Michigan.
- Proteovant has assembled a world-class team of scientists and drug developers with deep drug hunting capabilities in the field of small molecule degrader development to support its internal degrader discovery and development efforts. The core skill sets of the Proteovant team span all aspects of drug discovery and development, including medicinal chemistry, biology and structural biology, which is also supported by access to next generation wet labs.
- Proteovant has an exclusive partnership with VantAI, which, through its focus on *in silico* design, has developed a number of powerful and distinctive tools to support induced proximity related drug discovery, including:
  - A novel protein contact-first workflow that utilizes information about known protein-protein interactions to design new degraders that can effectively stabilize target-E3 interfaces;
  - A degron knowledge graph, which we believe to be industry-leading, that maps the ubiquitin proteasome system and enables the analysis of interactions between E3 ligases and degrons as well as the protein components that bind to E3 ligases and regulate degradation; and

- A unique model for predicting degradation based on millions of carefully curated protein stability datapoints.

- **Pipeline:**

- Proteovant has a broad pipeline of programs across oncology and immunology indications, and its protein degrader structures include heterobifunctionals and molecular glues. The protein degraders in Proteovant's pipeline range from early target validation through later stages of preclinical development. Select targets include STAT3, CBP/p300, and SMARCA2/4.
- In addition to Proteovant's wholly owned pipeline, Proteovant has an ongoing strategic collaboration with Blueprint Medicines, pursuant to which the two companies intend to advance up to two novel protein degrader compounds into development candidates. In addition, the collaboration includes an option to expand to up to two additional novel protein degrader target programs. As a part of the collaboration, VantAI will deploy its technology for degrader generation and optimization.

- **Development plan and upcoming milestones:**

- Proteovant aims to generate 1-2 INDs per year beginning in 2024.

- **Roivant ownership:**

- As of March 31, 2022, we own 60% of the issued and outstanding common shares of Proteovant and 54% on a fully diluted basis.

## Genevant Overview

- **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:**
  - Genevant has two delivery platforms: LNP and ligand conjugate.
    - LNP platform:
      - Proven technology as demonstrated by 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 lung, eye, central nervous system, and hepatic stellate and immune cells
      - Approximately 750 issued patents and pending patent applications as of June 15, 2022
    - Ligand conjugate platform:
      - Novel GalNAc ligands with demonstrated ability to deliver to the liver in preclinical studies
      - In preclinical head-to-head testing, demonstrated equal or better preclinical potency, assessed by duration and magnitude of knockdown, compared to a current industry benchmark
      - Applying delivery expertise to design novel extrahepatic ligands to expand therapeutic reach
- **Collaboration-based business model:**
  - Genevant uses its expertise in the delivery of nucleic acid therapeutics to develop optimal delivery systems for its collaborators’ identified payloads or target tissues.
  - Genevant collaboration-based business model is to seek some or all of upfront payments, R&D reimbursements, and milestones and royalties (or profit share) 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-license.
  - Some current collaboration partners include BioNTech, Takeda, Sarepta, Gritstone, ST Pharm, 2seventy bio, Chulalongkorn University (through its Vaccine Research Center), and Providence Therapeutics.
- **Clinical data:**
  - Genevant LNP technology has been in clinical testing in over a dozen distinct product candidates, representing hundreds of subjects of clinical experience.
  - Genevant LNP technology is included in the first RNA-LNP product to receive FDA-approval, Alnylam’s Onpattro (patisiran).
- **Roivant ownership:**
  - As of March 31, 2022, we own 83% of the issued and outstanding common shares of Genevant and 67% on a fully diluted basis.

### **Nucleic Acid Therapeutics**

Nucleic acid therapeutics represent an emerging modality that we believe may overcome challenges associated with traditional small molecule drug development in the treatment of genetically defined disease. The

vast majority of human proteins are considered “undruggable” by small molecules based on their protein structure. Nucleic acid therapeutics circumvent the question of whether or not a target is undruggable by impacting protein expression itself.

The field of nucleic acid therapeutics has gained significant momentum in recent years, with FDA approval of Alnylam’s Onpatro and Givlaari (givosiran), and approval of multiple mRNA COVID-19 vaccines. There is a substantial pipeline of nucleic acid therapeutics in clinical development that further underscores the transformative potential of nucleic acid therapeutics in the near term. However, nucleic acid therapeutics remain challenged by obstacles in the delivery of nucleic acids to specific cell types. RNA molecules cannot passively cross most cell membranes given their large size and negative charge, and therefore must be administered in conjunction with a delivery technology to ensure transport to target cell types.

We work with two proprietary technologies, LNP delivery and ligand conjugate delivery, to improve the likelihood of clinical success of nucleic acid therapeutics. We licensed intellectual property with respect to each of these technologies from Arbutus Biopharma in 2018.

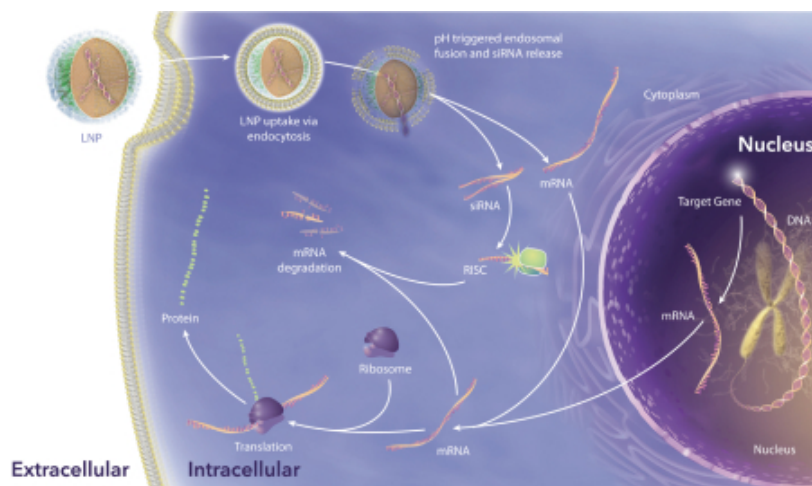
We are focused on expanding our platforms into novel tissue types by leveraging the scientific expertise of several members of the technical team that originally developed or advanced the technologies at Arbutus and its predecessors.

### Lipid Nanoparticle Platform

Our LNP technology platform is designed to deliver nucleic acids, including mRNA, siRNA, antisense and gene editing constructs.

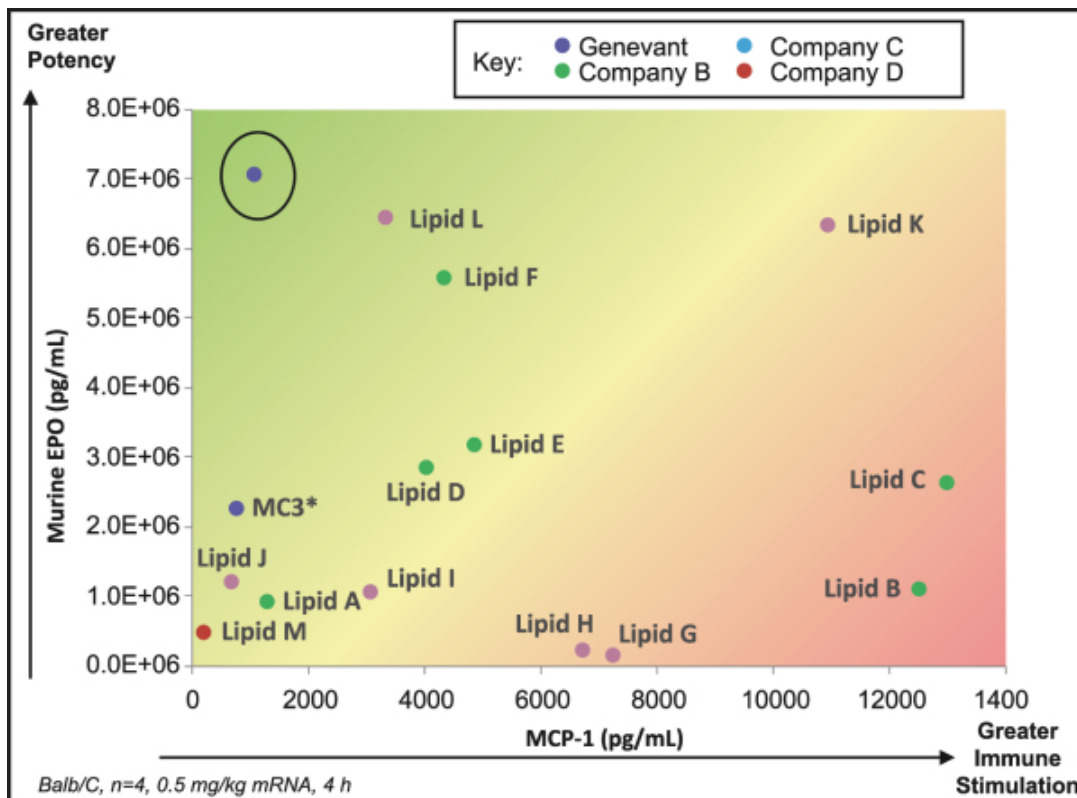
Some key features of our LNP technology are:

1. Multi-component formulations that contain specialized lipids optimized for potency and tolerability, are capable of encapsulating a broad range of nucleic acid payloads, and have limited constraints on nucleic acid composition, structure or size
2. A manufacturing process developed and scaled to produce stable uniform dispersion of colloidal nanoparticles with particle size appropriate for parenteral or intramuscular administration
3. Efficient intracellular delivery of nucleic acids to cell cytoplasm via engineered active endosomal escape mechanism



In a head-to-head study comparing multiple LNP formulations varying only the key ionizable lipid, a newer Genevant formulation outperformed third-party formulations. In particular, our formulation showed superior potency and avoidance of immune stimulation relative to others, including when compared with the LNP utilized in the first FDA-approved RNA-LNP therapeutic, Alnylam’s Onpattro (“MC3” in figure below).

**Genevant LNP Outperformed Third-Party LNPs in Head-to-Head Study**








\* Key lipid of first FDA-approved siRNA-LNP (Alnylam’s Onpattro)

In addition, Genevant LNP technology has entered the clinic with more than a dozen distinct product candidates, representing hundreds of subjects of clinical experience.



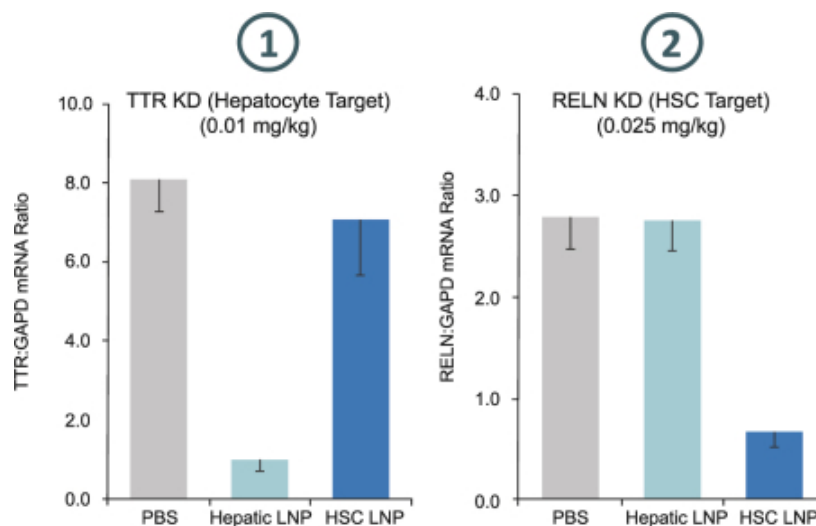
## Substantial clinical experience with Genevant LNP technology

Company	Product	Indication	Activity	Latest Phase
 Alnylam	ONPATTRO (patisiran)	ATTR Amyloidosis	<ul style="list-style-type: none"> <li>Safely dosed for up to 25 months in some patients</li> <li>Efficacy of up to 94% TTR knockdown with physiological effect</li> <li>Approved by the FDA August 2018</li> </ul>	Approved
 Arbutus	ARB-1467 (TKM-HBV)	Hepatitis B	<ul style="list-style-type: none"> <li>Completed Phase 2b trial in HBV patients</li> <li>Clear PD effect (knock down of surface antigen)</li> </ul>	Phase 2
	TKM-PLK1	Oncology	<ul style="list-style-type: none"> <li>Safely dosed for up to 18 months</li> <li>Evidence of anti-tumor activity based on a decrease in tumor size and a decrease in tumor density consistent with necrosis</li> </ul>	Phase 2
	TKM-Ebola (three LNP products)	Ebola Infection	<ul style="list-style-type: none"> <li>100% protection in lethal primate model of EVD</li> <li>Compassionate use in 2014 Ebola outbreak</li> </ul>	Phase 2
 Moderna	Four Prophylactic mRNA Vaccines	Various infectious diseases	<ul style="list-style-type: none"> <li>Successful completion of first in human mRNA vaccine trial</li> <li>Met primary endpoint of neutralizing Ab titers in healthy subjects</li> </ul>	Phase 1
 Gritstone	GRANITE-001	Oncology	<ul style="list-style-type: none"> <li>Personalized oncology vaccine; self replicating RNA payload encoding tumor neoantigens</li> <li>Promising immunogenicity activity and safety data released</li> </ul>	Phase 2
 Precedence	PTX-COVID19-B	SARS-CoV-2	<ul style="list-style-type: none"> <li>Promising immunogenicity activity and safety data released</li> </ul>	Phase 1

With this track record of success, we are now also focusing our LNP capabilities on historically challenging cell and tissue types, including hepatic stellate cells (“HSCs”).

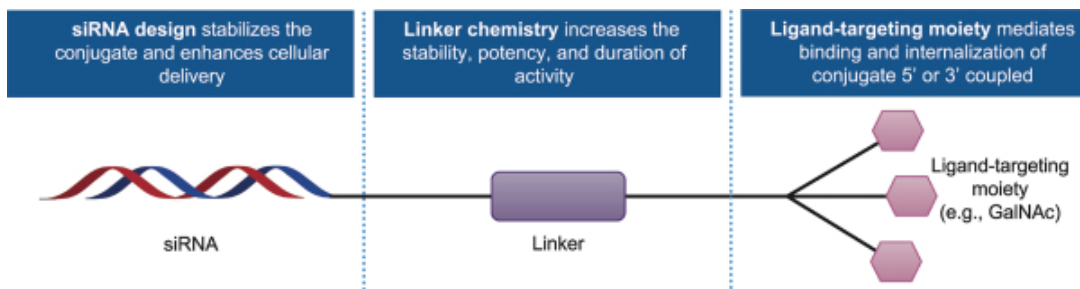
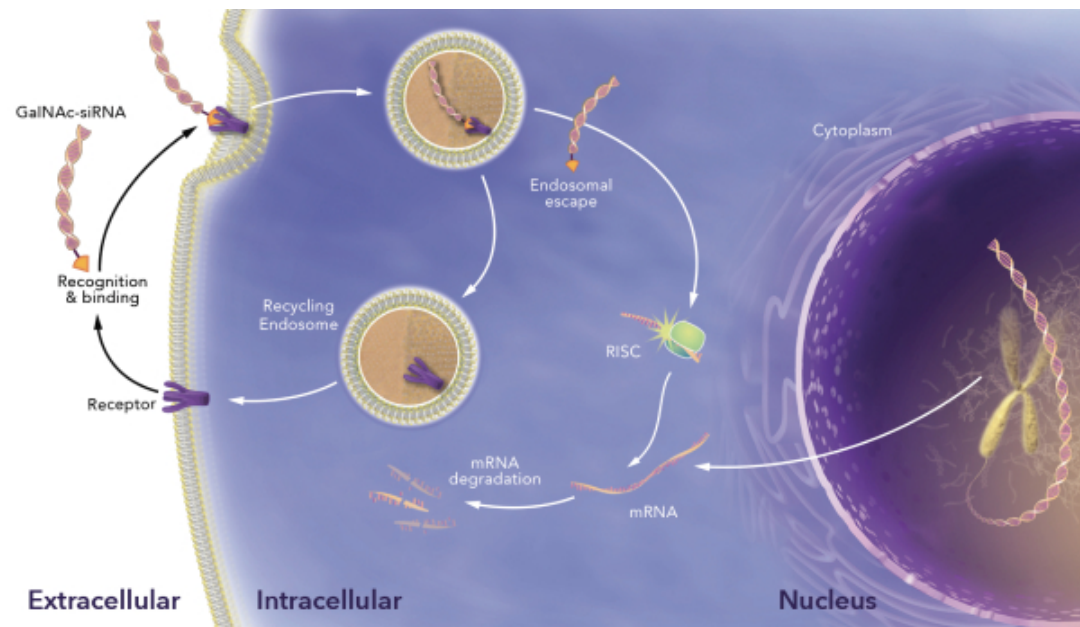
Historically, attempts to address certain diseases have been limited by the inability to access specific cell types outside of the hepatocyte. We have demonstrated our ability to deliver nucleic acid therapeutics to challenging targets by accessing HSCs in preclinical studies. The activation of HSCs is well established as a central driver of fibrosis, and thus technologies that target activated HSCs may be key to addressing certain liver diseases.

In preclinical studies, delivery of RNAi to HSCs via Genevant’s LNP technology demonstrated selective knockdown of an HSC target with minimal activity in hepatocytes, as shown below. Additional preclinical studies support our ability to design LNPs to deliver nucleic acids to the lung, and we believe that our scientific expertise will over time lead to the ability to direct LNPs toward additional cell and tissue types, such as the central nervous system, immune cells and the eye.



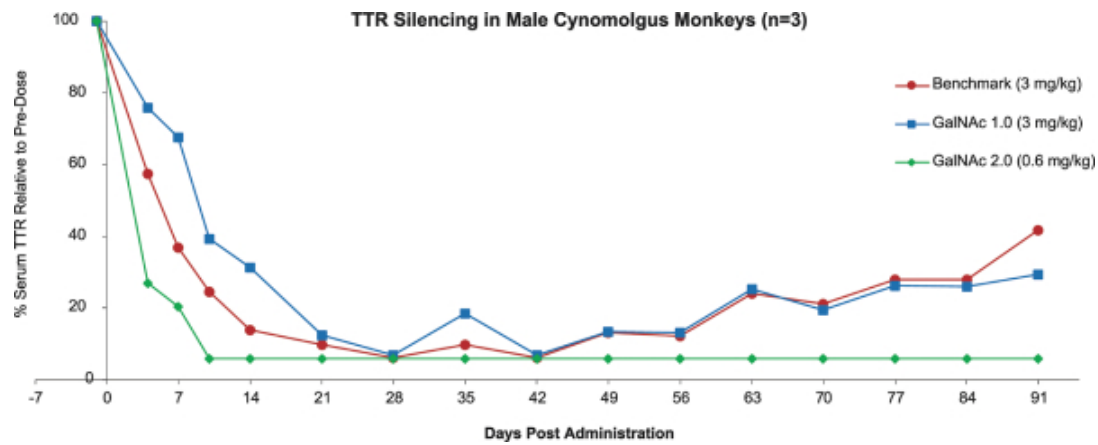
### Ligand Conjugate Platform

In addition to our LNP platform, we also have a proprietary RNAi ligand conjugate platform. Novel ligands can successfully deliver siRNA and certain other oligonucleotides to hepatocytes, and our expertise enables the design of novel ligands with the potential to expand delivery capability to other cell types such as hepatic stellate cells. Our ligand conjugate technology has demonstrated equal or better preclinical potency, assessed by duration and magnitude of knockdown compared to current industry benchmark. We currently have an allowed US patent and multiple patent applications pending with respect to our ligand conjugate platform.



We are developing a next-generation ligand conjugate platform that we refer to as “RNAi 2.0.” Our RNAi 2.0 platform has demonstrated superior strength and duration of knockdown compared to legacy ligand conjugates (“RNAi 1.0”) in a head-to-head preclinical study in nonhuman primates. In addition, our RNAi 2.0 platform:

- Contains intrinsic endosomolytic properties
- Has demonstrated marked *in vivo* enhancement in potency
- Has maintained a subcutaneous dosing regimen and is expected to be dosed subcutaneously in clinical trials
- Remains compatible with other ligand types



**Strategy**

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 innovative technologies while providing Genevant the opportunity to leverage our expertise to expand the technology and its therapeutic application.

This provides the following benefits to collaborators:

- Access to validated technology to deliver nucleic acid therapeutics for hepatocyte or vaccine applications
  - Potential to deliver RNA payloads to historically challenging-to-reach tissue or cell types, as well as nucleic acid design capabilities
  - No need to build internal delivery expertise or build intellectual property estate from scratch in an increasingly complex field

This provides the following benefits to Genevant:

- Opportunity to expand core delivery technology and capabilities, maintaining leadership position in nucleic acid delivery
- Typically, the ability to exploit certain rights to delivery-related intellectual property developed in the context of collaboration ourselves or with other collaborators
- Opportunity to generate revenue through deal structures including some combination of upfront payments, R&D reimbursements and additional milestones and royalties upon successful outcomes

To date, Genevant has partnered with leading companies with a shared vision of advancing innovative nucleic acid medicines to transform the lives of patients. Our collaborations currently include:

- **Gritstone**—Access to Genevant’s LNP technology for use in Gritstone’s self-amplifying RNA COVID-19 vaccine program
- **Gritstone**—Access to LNP technology for use with self-amplifying RNA for an unspecified indication

- **Sarepta**—Research collaboration and option agreement for the delivery of LNP-gene editing therapeutics for specified neuromuscular diseases; Genevant will design and collaborate with Sarepta in the development of muscle targeted LNPs to be applied to gene editing targets in multiple indications, including Duchenne muscular dystrophy
- **BioNTech**—Co-development in up to five rare diseases with high unmet medical need, and access to LNP technology for use with BioNTech’s mRNA for a specified number of oncology targets
- **Takeda**—Access to LNP technology to develop nucleic acid therapeutics directed to specified targets in HSC to treat liver fibrosis
- **Takeda**—Access to LNP technology to develop nonviral gene therapies for up to two rare liver diseases
- **ST Pharm**—Access to Genevant’s LNP technology for use in specified territories in ST Pharm’s mRNA COVID-19 vaccine program
- **Providence**—Access to Genevant’s LNP technology for use in Providence’s mRNA COVID-19 vaccine program
- **2seventy**—Access to LNP technology to develop gene editing therapies for hemophilia A
- **Chulalongkorn University**—Access to LNP technology for use in specified Asian territories in its mRNA COVID-19 vaccine program

### Potential Benefits of Genevant’s Delivery Platforms

- *Robust and expansive patent portfolio.* As of June 15, 2022, there are approximately 750 issued patents and pending patent applications for our LNP platform, including coverage directed to individual lipid structure, particle composition, particle morphology, manufacturing and mRNA-containing LNP formulations. As we continue to develop these technologies, we expect to have the opportunity to expand our intellectual property portfolio further, to enhance protection and support additional licensing opportunities.
- *Experienced leadership team.* Our leadership team has deep technical expertise in nucleic acid drug development and a track record of executing successfully in innovative areas. We believe this positions Genevant to expand delivery to historically challenging tissues and cell types, thereby creating potential opportunities for creative collaboration.
- *Manufacturing know-how.* Since inception, we have made strategic investments in expanding our manufacturing know-how. Our manufacturing process is rapid and reproducible, has intellectual property protection and is capable of commercial scale.

### Expansive Patent Portfolio

Our LNP platform is protected with a robust patent portfolio, covering a wide range of aspects required for successful nucleic acid delivery.

Our patents are directed to:

- Lipid structures, including cationic and PEG-lipids;
- Particle compositions, including commonly used ranges of lipid ratios for nucleic acid-containing particles;
- Nucleic acid-containing particles with certain structural characteristics;
- mRNA-containing LNP formulations; and
- Various aspects of our manufacturing process.

## Priovant Overview

- **Overview:**
  - Priovant is developing brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1, for the treatment of dermatomyositis (“DM”), systemic lupus erythematosus (“SLE”) and other immune-mediated diseases.
- **Lead program:**
  - Brepocitinib is a potentially first-in-class, orally administered, small molecule inhibitor of TYK2 and JAK1 that suppresses signaling of TYK2- and JAK1-dependent cytokines linked to autoimmunity, 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 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%.
  - SLE is a chronic, immune-mediated connective tissue disease that can impact nearly all major organ systems. The most common manifestations of SLE are cutaneous and musculoskeletal symptoms, although neurological, gastrointestinal, hematological, and renal symptoms are regularly observed as well. Patients with SLE are at a substantially increased risk of infection and cardiovascular disease, contributing to estimated 10- and 15-year mortality rates of 9% and 15%, respectively.
  - We estimate that there are approximately 37,000 adult DM patients and up to 300,000 adult SLE patients in the US.
- **Limitations of current treatments:**
  - Corticosteroids, disease-modifying antirheumatic drugs (“DMARDs”), and immunosuppressants, administered alone or in combination, are traditional therapies for patients with DM and SLE. 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 SLE who do not respond adequately to traditional therapies, belimumab (BENLYSTA) and anifrolumab (SAPHNELO) are FDA-approved biologic treatments. However, in each of belimumab’s BLISS Phase 3 program and anifrolumab’s TULIP Phase 3 program, the clinical trial data demonstrates that many patients failed to respond to these therapies, and both therapies are administered intravenously or subcutaneously.
- **Clinical data:**
  - Brepocitinib has been evaluated in five completed placebo-controlled Phase 2 studies in immune-mediated diseases (psoriatic arthritis, plaque psoriasis, ulcerative colitis, alopecia areata, and hidradenitis suppurativa). In all five of these studies, treatment with brepocitinib was associated with statistically significant and clinically meaningful efficacy.

<u>Study Population</u>	<u>N1</u>	<u>Brepocitinib Dose</u>	<u>Primary Endpoint Result</u>	<u>Statistical Significance</u>
Psoriatic Arthritis	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	P = 0.0197
Plaque Psoriasis	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI score at week 12	P < 0.0001
Ulcerative Colitis	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	P = 0.0005
Alopecia Areata	94 <sup>2</sup>	30 mg once daily <sup>3</sup>	49.18 placebo-adjusted CFB in SALT Score at week 24	P < 0.0001 <sup>4</sup>
Hidradenitis Suppurativa	100	45 mg once daily <sup>5</sup>	18.7% placebo-adjusted HiSCR rate at week 16	P = 0.0298 <sup>4</sup>

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 QD for 4 weeks followed by 30 mg QD for 20 weeks.
4. One-sided p-value (pre-specified statistical analysis).
5. Brepocitinib 45 mg once daily was the only dose evaluated in this study.

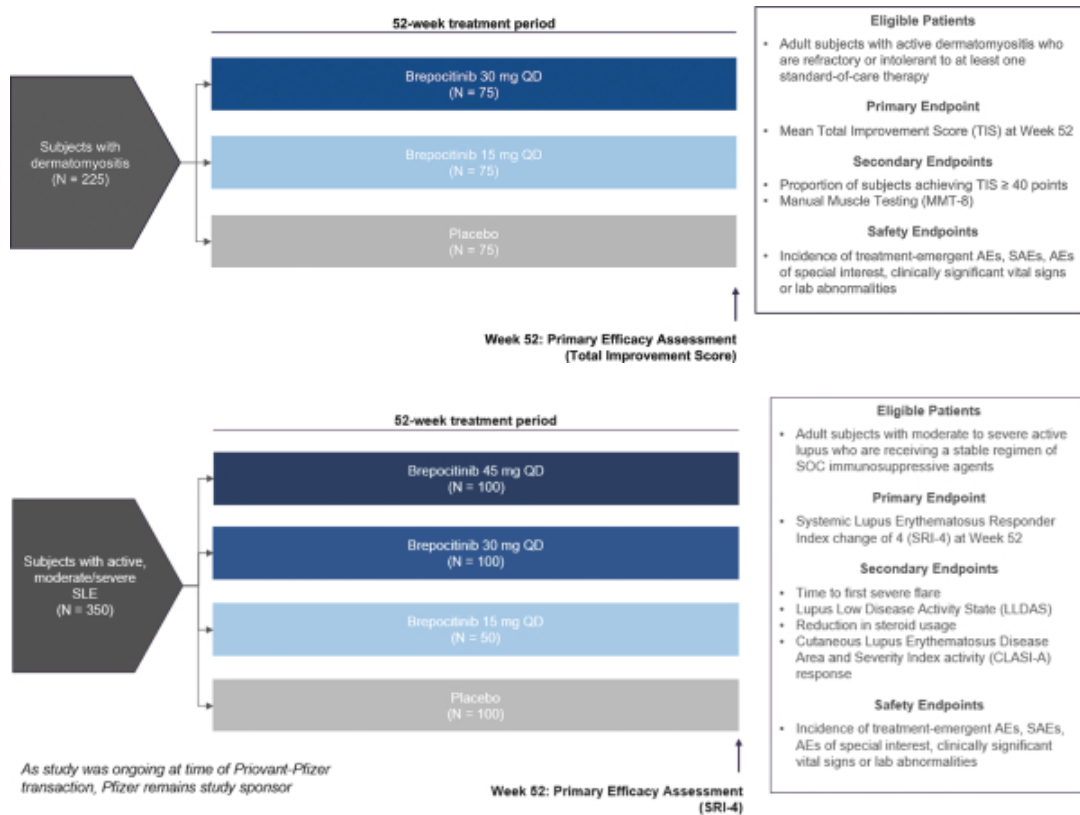
ACR20: American College of Rheumatology 20% Improvement; RR: Response Rate; CFB: Change From Baseline; PASI: Psoriasis Area and Severity Index; SALT: Severity of Alopecia Tool; HiSCR: Hidradenitis Suppurativa Clinical Response

- Brepocitinib’s safety database includes over 1,000 exposed participants evaluated in 14 completed Phase 1 and Phase 2 studies and three ongoing Phase 1 and Phase 2 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.
- Brepocitinib has not been evaluated in DM to-date. However, several FDA-approved JAK inhibitors have been clinically validated in DM patients refractory to standard-of-care therapies, as reported in more than 100 off-label case reports and in an open-label clinical trial. In addition, since DM pathobiology is driven by dysregulations in cytokines whose signaling is mediated by both TYK2 and JAK1, we believe that, with its unique dual inhibition of both TYK2 and JAK1, brepocitinib, as compared to inhibitors selective to either TYK2 or JAK1 has the potential to demonstrate superior clinical efficacy in DM.
- Brepocitinib has not been evaluated in SLE to-date. However, FDA-approved and investigational JAK inhibitors have completed successful proof-of-concept studies in SLE patients. And, like DM, SLE pathobiology is driven by dysregulations in cytokines whose signaling is mediated by both TYK2 and JAK1. We believe that, with its unique dual inhibition of both TYK2 and JAK1, brepocitinib, as compared to inhibitors selective to either TYK2 or JAK1, has the potential to demonstrate superior clinical efficacy in SLE.
- **Development plan and upcoming milestones:**
  - Priovant is currently conducting a large randomized, controlled Phase 3 study of brepocitinib in patients with refractory dermatomyositis. This study will enroll approximately 225 subjects in total and will evaluate 15 mg and 30 mg of brepocitinib once-daily compared to placebo. The primary endpoint of this study is the mean Total Improvement Score (“TIS”), a validated myositis improvement index, at Week 52.
  - Brepocitinib is currently being evaluated in a large, randomized controlled Phase 2B study in patients with moderate to severe active SLE. This study will enroll approximately 350 subjects in total and will evaluate 15 mg, 30 mg, and 45 mg of brepocitinib once-daily compared to placebo. The primary

endpoint of this study is the Systemic Lupus Erythematosus Responder Index (“SRI-4”), a validated SLE improvement index, at Week 52. Priovant anticipates receiving topline results from this study in the second half of 2023.

- Priovant is also evaluating brepocitinib for the development of hidradenitis suppurativa and non-infectious uveitis.
- **Roivant ownership:**
  - As of March 31, 2022, we own 75% of the issued and outstanding shares of Priovant and 70% on a fully diluted basis.

The below schematics show the trial designs for the ongoing DM Phase 3 and SLE Phase 2B trials:



*Note: The sample size for the SLE trial is subject to a protocol amendment which requires review and approval in multiple territories.*



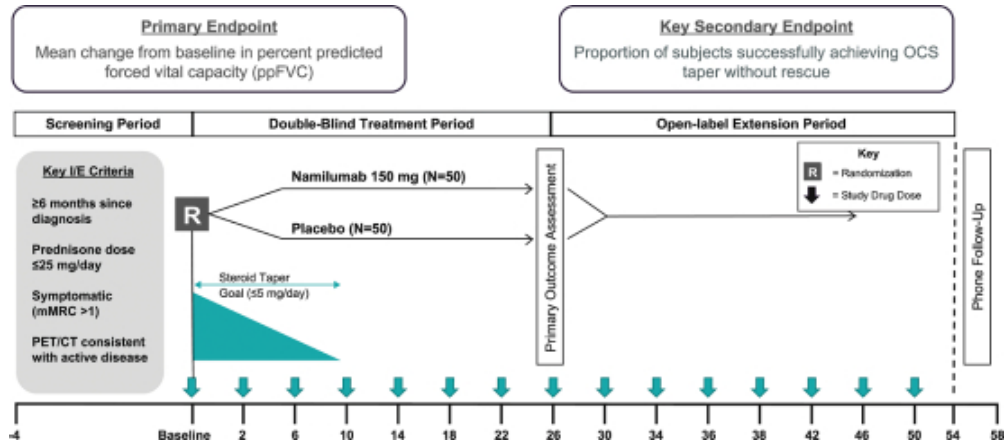
## Kinevant Overview

- **Overview:**
  - Kinevant is focused on developing namilumab for sarcoidosis and potentially other diseases.
- **Lead program:**
  - Namilumab is a fully human anti-GM-CSF monoclonal antibody with broad potential in inflammatory and autoimmune diseases being developed with potentially the least frequent dosing schedule among subcutaneous anti-GM-CSFs in Phase 2 clinical trials, with a single dose every four weeks after an initial loading period.
- **Disease overview:**
  - Sarcoidosis is a multi-system inflammatory disease characterized by the presence of non-necrotizing granulomas believed to be formed by an exaggerated immune response to unidentified antigens. Sarcoidosis primarily affects the lungs and lymphatic system, though sarcoidosis may damage any organ. GM-CSF, a key pathogenic cytokine, has been implicated in multiple parts of the granulomatous response.
  - Sarcoidosis affects approximately 200,000 people in the United States, with over 90% of cases presenting with pulmonary involvement.
  - An estimated 54% of pulmonary sarcoidosis patients are diagnosed, and approximately 90% of these patients receive some form of treatment. Market research with HCPs and third-party analysis of claims data suggest that approximately 25% of diagnosed and treated pulmonary sarcoidosis would be eligible for treatment with second-line or later therapy.
- **Limitations of current treatments:**
  - Corticosteroids are the most widely used treatment for sarcoidosis, but they carry significant side effects when used longer-term. Second- and third-line treatment options, including immunosuppressive therapies and biologics, are limited by slow onset, safety risk, inconsistent effectiveness, and reimbursement challenges, leaving significant unmet medical need that could be met by a novel biologic.
- **Clinical data:**
  - Early clinical data in pharmacokinetic/pharmacodynamic (PK/PD) and subsequent Phase 2 studies showed namilumab to be well-tolerated with a single subcutaneous injection given up to every four weeks.
  - In a Phase 1 study of healthy volunteers with a single subcutaneous injection, namilumab was observed to be generally well-tolerated.
  - In a Phase 2 trial in patients with moderate to severe rheumatoid arthritis conducted by Takeda, namilumab demonstrated decreased disease activity compared to placebo. In this trial, patients were given a subcutaneous injection of either 20, 80, or 150 mg of namilumab four times over a ten-week period. Over the 12-week study period, 14 of 27 (52%) subjects receiving placebo and 45 of 81 (56%) receiving namilumab experienced a treatment-emergent adverse event (TEAE). The most common TEAEs were nasopharyngitis, dyspnea, bronchitis, and headache.
- **Development plan and upcoming milestones:**
  - We have initiated a Phase 2 trial to evaluate the safety and efficacy of namilumab in pulmonary sarcoidosis, with a readout expected in the first half of 2024.

- **Roivant ownership:**

- As of March 31, 2022, we own 88% of the issued and outstanding common shares of Kinevant, and 83% on a fully diluted basis.

The below schematic shows the trial design for the Phase 2 trial in pulmonary sarcoidosis:



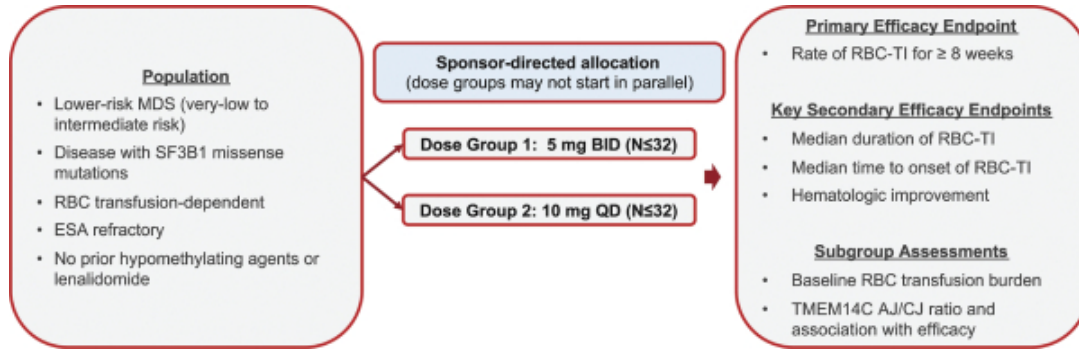
## Hemavant Overview

- **Overview:**
  - Hemavant is developing RVT-2001, a small molecule SF3B1 modulator, for the treatment of transfusion-dependent anemia in patients with lower-risk myelodysplastic syndromes (“MDS”).
- **Lead program:**
  - RVT-2001 is a potentially first-in-class, orally administered, small molecule SF3B1 modulator that corrects SF3B1 mutation-induced splicing defects in mRNA transcripts that encode proteins thought to be associated with the development of MDS.
- **Disease overview:**
  - Myelodysplastic syndromes are a group of hematologic malignancies in which immature blood cells in the bone marrow do not mature and become healthy blood cells. MDS patients are at risk for symptoms related to anemia, infection and bleeding, and they have variable survival expectations and rates of progression to acute myeloid leukemia. Assessment of prognosis is a key aspect in selecting therapy for the patient with MDS, and prognostic models broadly differentiate patients into either lower-risk MDS or higher-risk MDS.
  - We believe that there are approximately 115,000 MDS patients in the US, with approximately 17,000 new MDS cases per year, two thirds of which are lower-risk MDS.
- **Limitations of current treatments:**
  - Chronic anemia in patients with MDS requires regular and repeated red blood cell (“RBC”) transfusions, creating a significant burden for patients and an increased risk of organ toxicity from iron overload.
  - One of the primary goals of treatment is to reduce or eliminate RBC transfusion dependence while minimizing treatment-related toxicity. The first line of treatment for most lower-risk MDS patients consists of erythropoiesis-stimulating agents (“ESAs”), which are ineffective in over 50% of patients.
  - For patients who fail ESAs, the available treatment options depend on mutational status and disease phenotypes. In 2020, Reblozyl (luspatercept) became the only FDA-approved therapy for lower-risk MDS patients who are ring sideroblast positive and who have failed an ESA. Although Reblozyl can lead to transfusion independence, it is ineffective in over 50% of patients and is most effective in patients with a low transfusion burden. Reblozyl is delivered as an injection and is associated with numerous adverse events, including fatigue, a significant concern for patients already experiencing fatigue from anemia.
- **Clinical data:**
  - In the dose-escalation portion of an ongoing Phase 1/2 study, over 30% (6/19) of patients with lower-risk, transfusion-dependent MDS treated with RVT-2001 became RBC-transfusion independent (“RBC-TI”), with a median duration of treatment of approximately two years for responders. The dose-escalation portion of the study was conducted in a highly refractory patient population, which we believe may have decreased the observed treatment response relative to what would be expected in a less refractory target population.
  - In the dose-escalation portion of this ongoing Phase 1/2 study, which had a total of 84 patients with acute myeloid leukemia (“AML”), chronic myelomonocytic leukemia or MDS, RVT-2001 was observed to be generally well-tolerated, with the majority of events being classified as Grade 1.
- **Development plan and upcoming milestones:**
  - We have amended the IND for the ongoing open-label Phase 1/2 trial to add a dose-optimization cohort. We are enrolling a less refractory patient population in the dose-optimization cohort than the

population from which the first 19 lower-risk, transfusion-dependent MDS patients were drawn during the dose-escalation portion by excluding patients with prior exposure to lenalidomide or hypomethylating agents. We are targeting a genetically defined subpopulations by enrolling only lower-risk MDS patients with SF3B1 mutations. In addition, we are evaluating baseline expression of TMEM14C transcripts as a potential biomarker predictive of response to RVT-2001, since among the 7 MDS patients with the highest levels of aberrant TMEM14C transcripts in the dose-escalation portion of this Phase 1/2 trial, 71% (5/7) became RBC-TI. We also aim to strengthen the pharmacodynamic effect by optimizing the dosage of RVT-2001. We expect data from the dose-optimization cohort of the Phase 1/2 trial to be available in 2023.

- Our initial plan is to position RVT-3002 as second line therapy in SF3B1-mutated patients, with the potential to expand to other spliceosome mutations and ultimately first line treatment.
- **Roivant ownership:**
  - As of March 31, 2022, we own 100% of the issued and outstanding common shares of Hemavant and 100% on a fully diluted basis.

The below schematic shows the trial design for the dose-optimization cohort of our ongoing Phase 1/2 study:



## Affivant Overview

- **Overview:**

- Affivant is focused on the future development and commercialization of AFVT-2101 and other bispecific antibodies through its licensing and strategic collaboration agreement with Affimed to develop and commercialize novel innate cell engagers for multiple cancer targets.

- **Lead program:**

- AFVT-2101 is a preclinical immune-engaging bispecific antibody licensed from Affimed with potential applicability to several solid tumor indications.
- Bispecific innate cell engagers (“ICE”), which are generated by Affimed’s Redirected Optimized Cell Killing (“ROCK”) platform technology, are a novel class of drugs that activate the innate immune system and trigger a concerted anti-tumoral immune response. These bispecific antibodies consist of tumor-associated antigen binding domains, which cause high affinity and high specificity binding to the tumor surface, and immune cell binding domains, which bind and activate specific immune cell subsets able to kill the tumor cell.
- AFVT-2101 is an ICE program whose Fc region is fused to two high affinity CD16A binding single chain variable regions to maximize NK cell and macrophage engagement. The biological target of AFVT-2101’s tumor-associated antigen binding domain has been clinically validated via other targeted agents (mAb and ADC), including both evidence of single agent activity and a generally well-tolerated safety profile of the corresponding mAb in published studies.
- We believe AFVT-2101 has potential applicability across several highly prevalent solid tumor types, providing the optionality to pursue multiple large-market indications.

- **Preclinical data:**

- In a head-to-head preclinical study, AFVT-2101’s potency, as measured by target cell killing, exceeded that of a monoclonal antibody (“mAb”) that has been clinically validated against the same tumor target.
- AFVT-2101’s potency also exceeded the potency of antibody-drug conjugate (“ADC”) agents that have been clinically validated against the same tumor target, as reported in published preclinical studies.
- Based on preclinical and clinical experiences with other ICE antibodies in separate studies, we believe that the tolerability of AFVT-2101 has the potential to be superior to that observed to date with ADCs in published literature.

- **Development plan and upcoming milestones:**

- We expect to file an IND for AFVT-2101 in the first half of calendar year 2023.
- Pursuant to a collaboration and licensing agreement between Affivant and Affimed, Affimed is conducting a significant portion of the AFVT-2101 preclinical work for the collaboration under the governance of a Joint Steering Committee controlled by Affivant.
- Pursuant to the agreement Affivant will be responsible for submitting any IND or equivalent for AFVT-2101, and will be responsible for all future clinical development and commercialization worldwide, with Affimed retaining an option for co-promotion.
- We also have the option to license from Affimed additional ICE molecules directed against targets that are not (a) currently licensed or optioned to third parties or (b) directed against targets included in Affimed’s current pipeline.

- **Roivant ownership:**

- As of March 31, 2022, we own 100% of the issued and outstanding common shares of Affivant and 99% on a fully diluted basis.

## Asset Acquisition and License Agreements; Other Vant Agreements

### *Dermavant*

#### *GSK and Welichem Agreements*

In July 2018, our subsidiary Dermavant Sciences GmbH (“DSG”) acquired the worldwide rights (other than for China) with respect to certain intellectual property rights retained by Welichem Biotech Inc. (“Welichem”) to VTAMA and related compounds from Glaxo Group Limited and GlaxoSmithKline Intellectual Property Development Ltd. (collectively, “GSK”) pursuant to an asset purchase agreement (the “GSK Agreement”). GSK previously acquired rights to a predecessor formulation of VTAMA from Welichem pursuant to an asset purchase agreement between GSK and Welichem entered into in May 2012 (the “Welichem Agreement”). Under the GSK Agreement, DSG made an upfront payment of £150.0 million (approximately \$191 million) to GSK.

DSG is also obligated to pay GSK £100.0 million (approximately \$126 million on the date of achievement) within 70 days following the receipt of marketing approval of VTAMA in the United States. The GSK Agreement does not require DSG to pay any royalties on sales of VTAMA following commercialization or make any commercial milestone payments, except for milestones owed to Welichem as described below.

In addition, under the GSK Agreement, DSG assumed all obligations under the Welichem Agreement, including initially up to CAD\$180.0 million in potential development and commercial milestone payments, of which CAD\$80.0 million have been achieved and paid as of March 31, 2022.

In August 2018, in connection with the GSK Agreement, DSG and GlaxoSmithKline Trading Services Limited (“GSK Trading”) entered into a clinical manufacturing and supply agreement for VTAMA pursuant to which DSG obtained an existing supply of VTAMA drug product and drug substance as well as additional supply of VTAMA drug product for clinical trials on a cost plus basis. As required under the GSK Agreement, in April 2019, DSG and GSK Trading also entered into a commercial manufacturing and supply agreement (the “Commercial Supply Agreement”) pursuant to which DSG will obtain VTAMA drug product and drug substance from GSK Trading. Under the Commercial Supply Agreement, GSK Trading will provide development services to prepare for the manufacture and supply of VTAMA at commercial scale. DSG will obtain commercial supply of VTAMA on a cost plus basis under the Commercial Supply Agreement.

#### *Collaboration and License Agreement with Japan Tobacco Inc.*

In January 2020, DSG entered into a collaboration and license agreement with Japan Tobacco Inc. (“Japan Tobacco”) (the “Japan Tobacco Agreement”). Pursuant to the Japan Tobacco Agreement, DSG granted Japan Tobacco exclusive rights to develop, register and market tapinarof in Japan for the treatment of dermatological diseases and conditions, including psoriasis and atopic dermatitis. In connection with the Japan Tobacco Agreement, Japan Tobacco has signed an exclusive license with its subsidiary, Torii, for co-development and commercialization of tapinarof in Japan.

Under the Japan Tobacco Agreement, DSG has received (i) an upfront payment of \$60.0 million in January 2020 and (ii) a payment of \$10.0 million in December 2021 related to development milestones that were achieved, and DSG may receive up to an additional \$43.0 million upon the achievement of certain development milestones for tapinarof in psoriasis and atopic dermatitis. In addition, DSG will be entitled to tiered purchase prices specified in the Japan Tobacco Agreement in consideration of DSG’s commercial supply of tapinarof to Japan Tobacco under the terms of a separate commercial supply agreement to be negotiated by the parties. DSG also has the right to receive royalties, to be negotiated by the parties and consistent with the purchase prices, based on product sales of tapinarof in the indications to the extent that DSG is no longer responsible for supplying tapinarof to Japan Tobacco.

The Japan Tobacco Agreement will remain in effect until expiration of the obligation to pay royalties, unless terminated in accordance with the following: (1) for any reason by Japan Tobacco upon written notice to

DSG, which notice must be provided (x) at least 90 days in advance, if the termination is prior to regulatory approval of tapinarof in Japan for any dermatological disease or condition, and (y) at least 180 days in advance, if the termination is subsequent to regulatory approval of tapinarof in Japan for any dermatological disease or condition; (2) by either party upon written notice for the other party's material breach if such party fails to cure such breach within the specified cure period; or (3) by DSG if Japan Tobacco or its affiliates or sublicenses participate in a challenge to certain of our patents.

*Dermavant Financing Agreements—Dermavant Revenue Interest Purchase and Sale Agreement*

In May 2021, DSG, as seller, entered into a Revenue Interest Purchase and Sale Agreement (the "RIPSA") with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P. (collectively, the "Purchasers"), together with U.S. Bank National Association, as collateral agent.

In June 2022, following satisfaction of the funding conditions set forth in the RIPSA, including receipt of marketing approval from the FDA for VTAMA (received in May 2022), the Purchasers paid DSG a total of \$160.0 million in accordance with the terms and conditions set forth in the RIPSA (the "Purchase Price"). In consideration therefor, each of the Purchasers has the right to receive a low single-digit to high single-digit tiered percentage of quarterly revenues based on the achievement of specified net sales thresholds for VTAMA in the U.S., up to a cap of \$344.0 million. Payments of such quarterly revenues to the Purchasers under the RIPSA are secured by a security interest in certain VTAMA-related assets, including intellectual property rights and certain other assets that are owned by, licensed to or otherwise controlled by DSG related to the development and commercialization of VTAMA.

The RIPSA contains certain representations and warranties and covenants applicable to DSL and its subsidiaries. The RIPSA also contains certain Events of Default (as defined in the RIPSA) such as the breach of payment and other obligations, bankruptcy-related events and cross-defaults with respect to other related documents and agreements creating indebtedness. The occurrence of an Event of Default following the Purchasers' funding of the Purchase Price triggers DSG's obligation to pay an Event of Default Fee (as defined in the RIPSA) of \$160.0 million, less revenue payments previously paid, as liquidated damages. In addition, the occurrence of a change of control of DSG prior to the Purchasers funding the Purchase Price triggers DSG's right, but not the obligation, to terminate the RIPSA by payment of the Pre-Funding Change of Control Option Price (as defined in the RIPSA) to all of the Purchasers, which varies based on the date of termination and certain milestones with respect to VTAMA.

*Dermavant Financing Agreements—Dermavant Credit Agreement with XYQ Luxco*

In May 2021, our subsidiaries Dermavant Sciences Ltd. ("DSL"), Dermavant Holdings Limited, Dermavant Sciences IRL Limited and DSG, as borrowers (the "Borrowers"), and certain other subsidiaries of DSL, as initial guarantors, entered into a credit agreement (the "Credit Agreement") with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent. The Credit Agreement provides for a term loan of \$40.0 million (the "Term Loan"), the proceeds of which were used by the Borrowers to repay in full and terminate an existing credit facility with Hercules Capital Inc., with the remaining proceeds to be used for working capital and other general corporate purposes.

The Term Loan bears interest at a fixed interest rate of 10.0% per annum, with interest paid quarterly in arrears until maturity in May 2026, at which time the principal amount is due. The Borrowers have the option to prepay the Term Loan in whole or in part, subject to (i) until May 2023, a prepayment premium of 5.0% of the principal amount being repaid (plus the present value of all future scheduled interest on the principal being prepaid that would accrue through May 2023 calculated based on a discount rate equal to the treasury rate plus 100 basis points, except in the event the prepayment is due to a change of control), (ii) from May 2023 to May 2024, a prepayment premium of 5.0% of the principal amount being repaid, and (iii) from May 2024 to May

2025, a prepayment premium of 2.5% of the principal amount being repaid. From May 2025 through maturity, the Term Loan may be prepaid in whole or in part without a prepayment premium. Optional and mandatory prepayment of the Term Loan, as well as other forms of prepayment, repayment, applications or reductions, will also require that DSL pays an Exit Fee (as defined in the Credit Agreement), calculated based on the amount so prepaid, repaid, applied or reduced.

The Borrowers' obligations under the Credit Agreement are unconditionally guaranteed by the initial guarantors and secured by first priority security interests in substantially all of the tangible and intangible assets of the Borrowers and guarantors, including certain intellectual property rights, bank accounts, any and all insurance receivables, intercompany receivables and/or trade receivables and certain quotas and/or participation rights.

The Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings, including a covenant against the occurrence of a "change in control" (subject to the Borrowers' right to prepay the Term Loan), financial reporting obligations and certain limitations on indebtedness, liens (including on intellectual property and other assets), investments, distributions (including dividends), collateral, transfers, mergers or acquisitions, taxes, corporate changes and deposit accounts.

The Credit Agreement contains a minimum cash covenant that requires the initial Borrowers and the guarantors thereunder to maintain a minimum cash balance of \$10.0 million until the earlier of (a) a Qualified IPO (as defined in the Credit Agreement), (b) an Ultimate Parent Spinout (as defined in the Credit Agreement), and (c) the date that XYQ Luxco, in its capacity as a purchaser under the RIPSAs, has received cumulative payments from DSG under the RIPSAs in an aggregate amount equal to its pro rata portion of the funding amount thereunder. The Credit Agreement also contains customary events of default (subject, in certain instances, to specified grace periods) including, but not limited to, the failure to make payments of interest, premium, fees, indemnity or principal under the Term Loan, the failure to comply with certain covenants and agreements specified in the Credit Agreement, defaults in respect of certain other indebtedness and certain events relating to bankruptcy or insolvency. If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Term Loan may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 2% per year may be applied to the outstanding principal balance, and the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Credit Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Credit Agreement would automatically become due and payable.

On the closing date of the Term Loan and in accordance with the Credit Agreement, DSL issued to XYQ Luxco a warrant to purchase an aggregate of 1,199,072 common shares of DSL. The warrant is exercisable at any time until the earlier of (x) seven years from the date of issuance and (y) three years from the closing of an underwritten initial public offering of DSL's common shares pursuant to an effective registration statement. The warrant includes customary registration rights and customary anti-dilution provisions for the common shares underlying the warrant in respect of certain corporate events (including share splits, share combinations, share dividends and other recapitalization transactions).

#### ***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 (i) the non-exclusive right to manufacture and (ii) the exclusive, royalty-bearing right to develop, import and use the antibody referred to as IMVT-1401 and certain back-up and next-generation antibodies, and products containing such antibodies, and to commercialize such products, in the United States,



Canada, Mexico, the E.U., the U.K., Switzerland, the Middle East, North Africa and Latin America (the “HanAll Licensed Territory”), for all human and animal uses. RSG also received the right to grant a sublicense, with prior written notice to HanAll of such sublicense, to: (i) a third-party in any country in the HanAll Licensed Territory outside of the United States and E.U.; (ii) an affiliate of RSG in any country in the HanAll Licensed Territory; and (iii) a third-party in the United States and E.U. only after submission of a biologics license application in the United States 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 relating to such antibodies and products to develop, manufacture and commercialize such antibodies and products for use outside of the HanAll Licensed Territory.

In December 2018, Immunovant Sciences GmbH, (“ISG”) obtained and assumed all rights, title, interest and obligations under the HanAll Agreement from RSG, including all rights to IMVT-1401 in the HanAll Licensed Territory, for an aggregate purchase price of \$37.8 million. HanAll and RSG have agreed that neither they nor certain of their affiliates will clinically develop or commercialize certain competitive products in the HanAll Licensed Territory.

Under the HanAll Agreement, the parties may choose to collaborate on a research program directed to the research and development of next generation FcRn inhibitors in accordance with an agreed plan and budget. ISG is obligated to reimburse HanAll for half of such research and development expenses incurred by HanAll, up to an aggregate reimbursement amount of \$20.0 million.

Pursuant to the HanAll Agreement, RSG made an upfront payment of \$30.0 million to HanAll in December 2017. In May 2019, ISG achieved its first development and regulatory milestone, which resulted in a \$10.0 million milestone payment that ISG subsequently paid to HanAll in August 2019. ISG will be responsible for future contingent payments and royalties, including up to a maximum of \$442.5 million upon the achievement of certain development, regulatory and sales milestone events. ISG is also obligated to pay HanAll tiered royalties ranging from the mid-single digits to mid-teens on 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 (i) the date on which the last valid claim of the licensed patents that cover such licensed product in such country expires, (ii) the date on which the data or market exclusivity for such licensed product in such country expires or (iii) 11 years after the first commercial sale of such licensed product in such country. 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.

### ***Proteovant***

#### *Michigan Research Agreement*

In January 2018, our subsidiary Oncopia entered into a research agreement with the Regents of the University of Michigan (the “University of Michigan”) (the “Michigan Research Agreement”). Pursuant to the Michigan Research Agreement, Oncopia and the University of Michigan are collaborating to discover and optimize small molecule protein degraders. Any intellectual property developed under the Michigan Research Agreement that is directed to certain targets will be licensed by the University of Michigan to Oncopia pursuant to the Michigan License Agreement, as described below. Pursuant to the Michigan Research Agreement, Oncopia is obligated to provide a low eight-digit amount in funding between 2021 and 2023. Unless earlier terminated based on customary termination rights or extended by mutual agreement, the Research Agreement continues until December 2023.

## *Michigan License Agreement*

In November 2020, Oncopia entered into an amended and restated patent license agreement with the University of Michigan (the “Michigan License Agreement”), pursuant to which the University of Michigan granted Oncopia an exclusive, worldwide, sublicensable license under certain patents related to certain existing small molecule protein degraders and certain future small molecule protein degraders that may be developed under the Michigan Research Agreement to make, use and commercialize certain products covered by such patents. Such license grant is subject to, among other things, certain rights required to be granted under prior research or sponsorship agreements.

Under the Michigan License Agreement, Oncopia is obligated to pay the University of Michigan a low-to-mid single-digit royalty on net sales of each licensed product. Oncopia’s royalty obligations apply on a product-by-product, country-by-country basis and end upon the expiration of the last-to-expire valid claim of the licensed patents under the University of Michigan Agreement which covers such licensed product in such country. The patents and pending patent applications, if granted, currently licensed under the Michigan License Agreement are expected to expire as early as 2037, and as late as 2042, without giving effect to any potential patent term extensions or patent term adjustments. Oncopia is obligated to pay the University of Michigan minimum annual royalties in the low five-digit range from March 2021 until the first commercial sale of a licensed product, at which time such minimum annual royalties will increase to a low six-digit amount. Oncopia may also be obligated to pay up to a maximum of a high seven-digit amount in development and commercial milestone payments on a per product basis. Unless earlier terminated based on customary termination rights, the term of the Michigan License Agreement will continue until the expiration of the last-to-expire valid claim of the licensed patents.

## ***Genevant***

### *Cross-License Agreement with Arbutus Biopharma Corporation*

In April 2018, our subsidiary, Genevant Sciences Ltd. (together with its subsidiaries, “Genevant”), entered into a cross-license agreement with our affiliate, Arbutus Biopharma Corporation (“Arbutus”), which the parties amended twice in June 2018 (as amended, the “Arbutus Cross-License Agreement”). Pursuant to the Arbutus 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 GaINAc technology for RNA-based applications other than hepatitis B virus (“HBV”), and certain other excluded fields. The license is subject to certain rights which have previously been licensed by Arbutus to other third parties. Under the Arbutus Cross-License Agreement, Genevant granted back to Arbutus an exclusive, sublicensable, worldwide, irrevocable, perpetual, royalty-free license under the intellectual property licensed under the Arbutus Cross-License Agreement and certain intellectual property acquired by Genevant after the effective date of the Arbutus Cross-License Agreement for applications involving the treatment and prevention of HBV.

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) up to 20% of the Royalty-Related Receipts (as defined in the Arbutus Cross-License Agreement) 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 Arbutus Cross-License Agreement are expected to expire as early as 2023, and as late as 2039, without giving effect to any potential patent term extensions or patent term adjustments. Unless earlier terminated based on customary termination rights, the Arbutus Cross-License Agreement will continue until the expiration of Genevant’s royalty obligations.

In December 2021, Arbutus and Genevant Sciences GmbH, as an assignee of Genevant, entered into the third amendment (the “Amendment”) to the Arbutus Cross License Agreement, which, among other things, clarified the treatment of proceeds received by Genevant from an action for infringement by any third parties of Arbutus’s intellectual property licensed to Genevant. In such an infringement action, Arbutus would be entitled to receive, after deduction of litigation costs, 20% of the proceeds received by Genevant 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). The Amendment also clarified that, if a third-party sublicensee of intellectual property licensed by Genevant from Arbutus commercializes a sublicensed product, Arbutus becomes entitled to receive a specified percentage of certain revenue that may be received by Genevant for such sublicense, including royalties, commercial milestones and other sales related revenue, or, if less, tiered low single-digit royalties on net sales of the sublicensed product. The specified percentage is 20% in the case of a mere sublicense (i.e., naked sublicense) by Genevant without additional contribution and 14% in the case of a bona fide collaboration with Genevant.

### ***Hemavant***

#### *License Agreement with Eisai Co. Ltd.*

In November 2021, our subsidiary, Pharmavant 7 GmbH (“Hemavant”), entered into a license agreement with Eisai Co. Ltd. (“Eisai”) (the “Eisai License Agreement”). Pursuant to the Eisai License Agreement, Eisai granted Hemavant (i) an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and know-how and (ii) a non-exclusive, worldwide, sublicensable, royalty-bearing license under certain additional patents, know-how and inventions, in each case, to develop, manufacture and commercialize the compound known as RVT-2001 and products incorporating RVT-2001 (“licensed products”) for all human and animal uses.

Hemavant paid Eisai an upfront fee of \$15.0 million, consisting of (i) \$8.0 million in cash and (ii) newly issued Roivant Common Shares with a value of \$7.0 million. Hemavant may also be obligated to pay up to a maximum of \$65.0 million in development and regulatory milestone payments (with respect to the product for the first indication) and up to a maximum of \$18.0 million in payments (with respect to the product for each additional indication) and up to a maximum of \$295.0 million in commercial milestone payments. Hemavant may also be obligated to pay a tiered high single-digit to sub-teens royalty, subject to certain customary reductions, on net sales of licensed products. Hemavant’s royalty obligations apply on a licensed product-by-licensed product, country-by-country basis commencing on the first commercial sale of such licensed product in such country and ending upon the latest of (i) the date on which the last valid claim of the licensed patents that cover the licensed product in such country expires, (ii) ten years after the first commercial sale of such licensed product in such country and (iii) the date on which the regulatory exclusivity for such licensed product in such country expires. Unless earlier terminated based on customary termination rights, the Eisai License Agreement will continue in effect until it expires (i) on a licensed product-by-licensed product and country-by-country basis upon the expiration of the royalty term with respect to such licensed product in such country and (ii) in its entirety upon the expiration of all applicable royalty obligations with respect to all licensed products in all countries.

### ***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, Inc. (“Pfizer”) (the “Pfizer License Agreement”). Pursuant to the Pfizer 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 Brepo 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) Brepo and products incorporating such compound outside of the U.S. and Japan, and (y) TYK2 compounds and products incorporating such compound 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 products in the applicable country, (b) the date on which the regulatory exclusivity provided by the applicable government authority for the applicable products 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 for the other party's uncured breach and Priovant has the right to terminate for convenience.

## **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for current and future products and 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 us 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 United States or in Europe, among other countries. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. 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 issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our product candidates 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 current and future products and product candidates and practicing our proprietary technology.

Our issued patents and those that may issue 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 current and future products and 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***

#### *Dermavant*

As of May 1, 2022, DSG is the exclusive owner of patent families that include six issued U.S. patents and at least 10 pending U.S. patent applications, as well as more than 25 issued patents and more than 50 pending patent applications in other jurisdictions, including the European Union and Japan, relating to VTAMA, the synthesis of VTAMA, intermediates made in the synthesis, the drug substance crystal form, topical formulations of VTAMA and uses thereof in certain diseases and disorders.

One of these patent families is directed to the topical formulation of VTAMA, and its use to treat plaque psoriasis, that Dermavant has evaluated in Phase 3 clinical trials, as well as its use to treat atopic dermatitis which has been evaluated in Phase 2b clinical trials, which includes a patent that was issued in the United States and has a natural expiration date in 2036, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. This formulation patent includes 113 claims directed to topical, homogeneous, oil-in-water micro-emulsions containing VTAMA, an oil phase, a surfactant and other specific ingredients. DSG also owns an issued patent in the United States covering methods of using the patented formulations to treat inflammatory diseases, including psoriasis and atopic dermatitis. Like the formulation patent, the method-of-use patent has a natural expiration date in 2036 in the United States, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The foreign counterpart formulation and method-of-use applications are pending, and if patents issue from these applications, they will also have a natural expiration date in 2036, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

DSG also owns a drug substance (“DS”) patent in the United States covering the high purity crystal form of VTAMA, as DS, the DS synthesis and several novel intermediates that are formed in the synthesis. This DS patent has a natural expiration date in 2038, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. DSG has also filed foreign counterpart DS applications that are still pending in foreign jurisdictions and, if patents issue from these applications, they will similarly have a natural expiration date in 2038, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

#### *IMVT-1401*

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 is the exclusive licensee of technology directed to IMVT-1401, and certain back-up and next-generation antibodies, and products containing such antibodies, in the licensed territory. As of May 1, 2022, the patent portfolio

includes pending patent applications and/or issued patent(s) in the United States and numerous foreign jurisdictions. The in-licensed patent portfolio includes a patent family that discloses anti-FcRn antibodies, 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. This patent family includes an issued U.S. patent with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, and a pharmaceutical composition comprising such antibody or antigen-binding fragment thereof as well as a second issued U.S. patent with claims directed to an isolated anti-FcRn antibody or antigen-binding fragment thereof, a pharmaceutical composition thereof as well as methods of treating various autoimmune diseases using such antibody or antigen-binding fragment, polynucleotides and expression vectors encoding the same, host cells capable of expressing the same and methods of producing such antibody or antigen-binding fragment. The patents and pending applications of this patent family, if issued, are expected to expire as early as 2035, in each case without taking into account any possible patent term adjustment or extensions 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 formulation for an anti-FcRn antibody with any patent issued therefrom expected to expire in 2041. For information regarding ISG's license agreement with HanAll, please see "—Asset Acquisitions and License Arrangements."

Additionally, as of May 1, 2022, independent of the licensed patent portfolio, ISG has a patent family directed to methods of treating thyroid eye disease using anti-FcRn antibodies that includes patent applications in the United States as well as foreign counterparts in certain jurisdictions within its licensed territory and another patent family that includes an internationally filed patent application directed to methods of treating warm autoimmune hemolytic anemia using anti-FcRn antibodies. Any patent issued from these patent families is expected to expire in 2039 and 2040, respectively, exclusive of any patent term adjustment or extension.

#### *Proteovant*

As of May 1, 2022, we own, co-own or have licensed rights to 28 patent families containing four issued U.S. patents, two issued European patents, 26 patents in a number of other jurisdictions and containing at least 80 pending patent applications in the U.S., Europe and a number of other jurisdictions. These patents and pending applications, if issued, are expected to expire as early as 2037, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

#### *Genevant*

As of May 1, 2022, we own or co-own 18 patent families containing at least 44 issued patents and at least 64 pending patent applications in the U.S., European Union and numerous other jurisdictions, including claims relating to lipid nanoparticle delivery technology and polymers. These patents and pending applications, if issued, are expected to expire between 2024 and 2041, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of May 1, 2022, we have licensed 37 patent families containing at least 479 issued patents and at least 217 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 2021 and 2039, in each case without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

#### *Hemavant*

As of May 1, 2022, Hemavant has exclusively licensed rights to four patent families containing at least 87 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 polymorph, methods of treating MDS, and biomarkers for MDS. These exclusively licensed 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 adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of May 1, 2022 Hemavant has non-exclusively licensed rights to three patent families containing at least 12 issued patents and 28 pending patent applications in the U.S. and other jurisdictions with claims covering methods of treating splice mutant cancers, spliceosome mutations, and combinations of a spliceosome modulator and a BCL inhibitor. The non-exclusively licensed 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 adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

#### *Priovant*

As of May 1, 2022, Priovant Therapeutics, Inc. has (1) exclusively licensed rights to four patent families for brepocitinib containing at least 149 issued patents and 77 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering a composition of matter, a crystalline form, a topical formulation, and a process for making 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 adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees, and (2) exclusively licensed rights to four patent families for brepocitinib containing at least 105 issued patents and 65 pending patent applications in the U.S. and other jurisdictions, including the European Union and Japan, with claims covering a composition of matter, a method of treating hidradenitis, a method of treating ulcerative colitis, 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 adjustment 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 United States 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 United States, 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 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 products and our reputation.

Our product candidates must be approved by the FDA through either an NDA or a BLA (as defined below) process before they may be legally marketed in the United States. 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 at 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/or us as the sponsor;
- payment of user fees for FDA review of the NDA or BLA (unless a fee waiver applies);
- agreement with 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 United States.

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 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](http://www.clinicaltrials.gov) website.

A sponsor who wishes to conduct a clinical trial outside of the United States 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/or 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 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 its 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 United States.

Under the Prescription Drug User Fee Act (the "PDUFA"), as amended, each NDA or BLA must be accompanied by a user fee. 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 product 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 has significantly curtailed its inspection program. The reduction in pre-approval inspections has resulted in delays to some product approvals. Even with the increase in FDA inspections, there may be delays to product approvals in the future based on a resurgence of 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 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/or 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 United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States 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 or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States 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 has extended the PRV program through September 30, 2024, with the potential for PRVs to be granted through September 30, 2026.

### ***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 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. 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. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

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 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, breakthrough therapy and RMAT 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 (the "FDASIA"), 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/or other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and 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 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 and commercial quantities of our products 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; or
- 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, often 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 United States, 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 application (“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 System Regulation (the “QSR”), 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 quality system regulation, 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.

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. FDA has recognized that contemporaneous clearance or approval of a companion diagnostic with a therapeutic is not always possible, though FDA has indicated that coordination of contemporaneous clearances/approvals is a policy goal. In October 2018, FDA issued a safety alert warning against the use of unapproved or uncleared genetic tests to predict patient response to specific medications. While FDA has historically exercised enforcement discretion against laboratory developed tests—tests which are developed and performed in a single Clinical Laboratory Improvement Amendments ("CLIA") certified laboratory—the 2018 alert and a subsequent 2019 Warning Letter against Inova Genomics Laboratory suggest that FDA may prioritize for enforcement certain uncleared or unapproved tests marketed as companion diagnostic tests. Subsequently, 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 June 2021, the Verifying Accurate Leading-edge IVCT Development Act of 2021 (the "VALID Act") was introduced in the U.S. House of Representatives and Senate. Similar to the 2020 iteration of the bill, among other things, the VALID Act would likely classify all companion diagnostic tests as requiring FDA premarket review and would formalize and arguably expand FDA's regulatory authority over diagnostic testing. Though passage of the VALID Act is uncertain, strong bipartisan support remains for some kind of diagnostic testing legislative reform in the near term.

### ***Biosimilars and Exclusivity***

Certain of our product candidates, including IMVT-1401, 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 Affordable Care Act (the "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, pose significant hurdles to implementation that are still being worked out by the FDA.

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 United States. 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 United States 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 payers, 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 United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and 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 products, 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 and security 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/or 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 United States 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 March 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the changes made by the ACA to preexisting law of importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price ("AMP"), and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.
- imposed a requirement on manufacturers of branded drugs to provide a 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.
- expanded the entities eligible for discounts under the 340B Drug Discount Program.
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Most recently, the Supreme Court upheld the constitutionality of the law in June 2021; however, future legal disputes remain possible. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA, and the law may be subjected to various Executive Orders and/or regulatory action to expand or reduce the scope of the law, based on the administration controlling the White House. The implementation of the ACA is ongoing, and the law may continue to exert significant pressure on pharmaceutical pricing and our profitability.

Moreover, in May 2018, the Trump administration released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint, and former President Trump also issued a number of Executive Orders in 2020 that were aimed at lowering the prices of prescription drugs. Some rules enacted under the Trump Administration have been stayed as a result of pending litigation or are under review or have been rescinded by the Biden Administration and/or Congress. For example, a rule enacted under the Trump Administration known as the "Most Favored Nations" rule would set Medicare Part B reimbursement at an amount no higher than the lowest price that a drug manufacturer receives on a particular product in an index of foreign countries. This rule currently was the subject of litigation, and was formally rescinded the Biden Administration in August 2021. Other initiatives under the Trump administration have taken effect. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a form of drug utilization management, for Part B drugs beginning January 1, 2020.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers 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 2029 unless additional congressional action is taken. However, pursuant to the CARES Act and subsequent legislation, these reductions were suspended starting on May 1, 2020 due to the COVID-19 pandemic. Recently enacted legislation extended the suspension through March 2022, with a 1% cut through the end of June 2022, after which the cuts would return to 2% unless additional Congressional action is taken. Additionally, the American Rescue Plan Act of 2021 eliminates the Medicaid unit rebate cap effective as of January 1, 2024, and the removal of this rebate cap could significantly impact our Medicaid rebate liability beginning in 2024.

There also have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, require drug pricing negotiations in Medicare, redesign the Part D benefit to lower patient costs and overall spending, introduce enhanced transparency measures into drug pricing, and reform government program reimbursement methodologies for drugs, for example, by introducing inflationary penalties for Parts B and D drugs. The Biden Administration has indicated that lowering prescription drug prices is a priority. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Additionally, on November 19, 2021, the House passed the Build Back Better Act, which among other provisions, would permit the Secretary of HHS to negotiate certain high-expenditure Part D drugs, impose inflationary rebates for Part D drugs, and redesign the Part D benefit. The Senate Finance Committee introduced a modified version of the legislation on December 11, 2021, but negotiations have since stalled. Although the House and Senate versions of this legislation would grant certain exceptions for "small biotech drugs" and "specified small manufacturers," if passed, we cannot predict how these exceptions would be implemented and their impact on Roivant. Ultimately, we cannot predict whether these or other drug pricing initiatives will be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect 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 products, which in turn may increase the volatility of our revenues as a reflection of changes in inventory volumes.

#### ***Packaging and Distribution in the United States***

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, 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 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 product candidates, 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 United States 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 United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable in the United Kingdom. However this ended on December 31, 2020. On December 30, 2020, the United Kingdom and European Union signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties. Since the regulatory framework in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorizations, commercial sales, and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the United Kingdom in the long term. The MHRA has published detailed guidance for industry and organizations to follow now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products and medical devices evolves over time. There are also a number of ongoing consultations on the future legislation in the UK.

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

Similar to the United States, the various phases of preclinical and clinical research in the EEA and United Kingdom are subject to significant regulatory controls. The EU Clinical Trials Directive 2001/20/EC (the "Directive") sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently into their national laws, including in the UK. This has led to significant variations in the Member State regimes. Under this regime, before a clinical trial can be initiated it must be



approved in each of the EU/UK countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (the “NCA”), and one or more Ethics Committees (“ECs”). Under this regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the country where they occurred.

The EU clinical trials legislation is undergoing a transition process due to the application of a new Clinical Trials Regulation (EU) 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 EU adopted the Regulation, which started to apply on January 31, 2022 and replaced the current Directive. Specifically, the new Regulation, which is directly applicable in all Member States without the need for EU Member States to transpose it into national law, aims at simplifying and streamlining the approval of clinical trials in the EU. 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.

Following Brexit, this Regulation is not applicable in the UK, and the national legislation put in place to implement the Directive continues to apply to trials conducted in the UK.

### ***European Union and United Kingdom Drug Marketing***

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and/or 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 United Kingdom. EU Directive 2001/83/EC, which is the Directive governing medicinal products for human use, as implemented in the relevant Member State and the UK, the national anti-bribery laws of the European Union Member States, and the Bribery Act 2010 in the UK, as well as the industry Codes of Practice that are based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice, collectively govern the provision of benefits or advantages to induce or reward improper performance. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the Directive governing medicinal products for human use, 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 EU Member States, as well as in the UK Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Depending on the applicable national rules in the EU Member States and the UK, payments and other transfers of value made to physicians, physician associations, medical students, healthcare organizations, patient organizations and other stakeholders in the EU Member States, the UK 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/or 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 EU 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 States 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 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.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain is no longer covered by centralized MAs (under the Northern Irish Protocol of the Withdrawal Agreement, centralized MAs will continue to apply in Northern Ireland). All medicinal products with a valid centralized MA as of December 31, 2020 were automatically converted to MAs valid in Great Britain on January, 1 2021 (unless the MA holder opted out of this procedure). For a period of two years from January 1, 2021 (although this may be extended), the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new MA valid in Great Britain. A separate application will, however, still be required and the MHRA has the right to undertake its own assessment of the dossier. The MHRA also has the power to have regard to MAs approved in EEA Member States through decentralized or mutual recognition procedures with a view to more quickly granting a MA in the United Kingdom or Great Britain.

#### ***European Union and United Kingdom Data Protection and Market Exclusivity***

In the EEA and UK, 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 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/UK, for a period of eight

years from the date 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 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).

#### ***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 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.

The upcoming legislative reforms in the EU, which are part of the new EU Pharmaceutical Strategy and some of which could materialize in 2022, may result in a reduction of market exclusivity periods for orphan medicinal products, and or imposition of additional requirements for grant of such exclusivity. In addition, the strategy envisages changes to the concept of unmet medical need and considers introducing novel rewards for medicines addressing an unmet medical need.

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

### ***European Union and United Kingdom Pediatric Investigation Plan***

In the EEA and UK, 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 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 EU, which are part of the new EU Pharmaceutical Strategy may result in a reduction of the above pediatric rewards and/or 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 United States. Until recently, one such data transfer mechanism was the EU-US Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the CJEU. The CJEU upheld the validity of standard contractual clauses (“SCCs”) as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA and the U.K., need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. It remains to be seen whether SCCs will remain available and whether additional means for lawful data transfers will become available. Moreover, the competent authorities and courts in a number of EU Member States increasingly scrutinize and question the GDPR compliance of processing of personal data by US-based entities or entities with links to US-based entities, independently of whether personal data is actually transferred outside the EEA. 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 EU Member States may, under certain strict conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross-border processing activities, even

such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority.

In addition, further to the United Kingdom's exit from the European Union on January 31, 2020, the GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the United Kingdom's data protection regime, which is independent from but aligned to the European Union's data protection regime. Non-compliance with the UK 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 United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

### ***Rest of the World Regulation***

For other countries outside of the European Union and the United States, 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, operating restrictions and

### ***Additional Laws and Regulations Governing International Operations***

If we further expand our operations outside of the United States, 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 United States 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 UK 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 United States, 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 United States, 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 products and product candidates outside of the United States, 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 products or any drugs that we may develop and commercialize. 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 will take 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. This regulation is subject to ongoing litigation; however, we cannot predict if the rule ultimately will be overturned or rescinded. 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 United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the acquisition costs and reimbursement for drug products may lower than within the United States.

In the United States, 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.

Further, due to the COVID-19 pandemic, millions of individuals have lost or are expected to lose employer-based insurance coverage, which may adversely affect our ability to successfully commercialize our products.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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, 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. Additional legislation surrounding the 340B program, including which providers are eligible for the program, may be enacted in the future. These developments could affect our profitability.

Moreover, there also is significant uncertainty related to the insurance coverage and reimbursement of cell or genetic therapy products. Although a new rule finalized by CMS for the Medicaid Drug Rebate Program increased flexibility regarding the manner in which manufacturers may offer value-based discounting arrangements, and following a regulatory delay, is expected to take effect on July 1, 2022.

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 United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union and UK, 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, 2022, we and our subsidiaries had approximately 863 full-time employees, including 791 in the United States.

Our human capital objectives include sourcing, recruiting, retaining, incentivizing and developing our existing and future employees. We seek to create nimble, entrepreneurial Vants that 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 and calculated risk-taking. In connection with becoming 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 Suite 1, 3rd Floor, 11-12 St. James's Square, London SW1Y 4LB, 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](http://www.sec.gov). References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC.

We are an "emerging growth company" (an "EGC"), as defined in the Jumpstart Our Business Startups Act of 2012. As an EGC, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation.



## 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the 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.*

### Risks Related to Our Business and Industry

#### *Risks Related to Our Financial Position and Strategy*

***Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development may make it difficult for us to execute on our business model and for you to assess our future viability. We have not generated significant revenue from our operations since inception, and there is no guarantee that we will do so in the future.***

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

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

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

- successfully commercialize VTAMA;
- identify new acquisition or in-licensing opportunities;
- successfully complete ongoing preclinical studies and clinical trials and obtain regulatory approvals for our current and future products and product candidates;
- successfully identify new product candidates through our small molecule discovery engine and advance those product candidates into preclinical studies and clinical trials;
- successfully market our healthcare technology products and services;
- raise additional funds when needed and on terms acceptable to us;
- attract and retain experienced management and advisory teams;
- add operational, financial and management information systems and personnel, including personnel to support clinical, preclinical manufacturing and commercialization efforts and operations;

- launch commercial sales of future product candidates, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of products and product candidates manufactured at acceptable cost and quality levels and in compliance with the U.S. Food and Drug Administration (the “FDA”) and other regulatory requirements;
- set acceptable prices for products and product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of products and product candidates in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

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

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development, or if there are any delays in any of our or our future collaborators’ clinical trials or the development of our product candidates that we may identify. We anticipate incurring significant costs associated with commercializing VTAMA and any future product candidates, if approved, as well as ongoing compliance efforts.

We may never be able to develop new marketable drugs or successfully commercialize a marketable drug or achieve profitability. To become profitable, we must succeed in developing and commercializing products that generate significant revenue. Revenue from the sale of any products or product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we have or may gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price, the strength and term of patent exclusivity for the product, the competitive landscape of the product market, and whether we own the commercial rights for that territory. For example, even though VTAMA for the treatment of adults with plaque psoriasis has received regulatory approval in the U.S., we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize VTAMA in other indications or in other jurisdictions. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, expand our pipeline, market our products and, if approved, product candidates, and continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders’ equity and working capital.

***We may never achieve or maintain profitability.***

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. While we have received regulatory approval for one product candidate, VTAMA for the treatment of adults with plaque psoriasis in the U.S., we have yet to receive marketing approval for any of our other product candidates anywhere in the world and we have not generated meaningful product revenues from the commercial sale of our biopharmaceutical products. We cannot estimate with precision the extent of our future losses. We may never generate meaningful product revenue from the commercial sales of our products or,

if approved, product candidates or achieve or maintain profitability. It is possible that we will continue to incur substantial operating losses for the foreseeable future. Our ability to generate meaningful product revenue and achieve profitability is dependent on the ability to complete the development of our products and product candidates, obtain necessary regulatory approvals for our current and future products and product candidates and manufacture and successfully market our current and future products and product candidates alone or in collaboration with others.

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

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

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

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

- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future products or product candidates; and
- our ability to hire, attract and retain qualified personnel.

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

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

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

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

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

- our ability to recruit and retain effective sales, marketing and customer service personnel;
- our ability to obtain access to physicians or persuade adequate numbers of physicians to prescribe VTAMA and any future products;
- the inability to manufacture and to price VTAMA and any future products at a price point sufficient to ensure an adequate and attractive level of profitability;
- the extent to which coverage and adequate reimbursement for these products will be available from government health administration authorities, private health insurers and other organizations;

- the risks associated with potential co-promotion or partnership agreements, including the failure to realize the expected benefits of such arrangements; and
- other unforeseen costs, expenses and risks associated with the commercialization of biopharmaceutical products, including compliance costs.

In addition, in preparation for our commercial launch of VTAMA, we expect to significantly increase the amount of cash we spend in order to expand our commercial infrastructure. We expect this level of increased cash spending to increase into calendar year 2023. The increased level of cash spending will support our transition to an integrated commercial biopharmaceutical company and to support the commercialization of VTAMA. To the extent that we are able to gain regulatory approval for VTAMA in any other jurisdiction besides the U.S. or to gain regulatory approval for any of our other product candidates in any jurisdiction, we would expect to incur additional increased cash costs.

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

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

The success of our business depends in part on our ability to successfully identify new product candidates, whether through acquisitions or in-licensing transactions or through our internal discovery capabilities. Our acquisition and in-licensing efforts focus on identifying assets in development by third parties across a diverse range of therapeutic areas that, in our view, are underserved or undervalued. Our strategy often entails designing low-cost studies that result in quick “go/no-go” decisions when deciding whether or how to proceed with future development for a given asset, once acquired. We may decide to proceed with the development of a product candidate on this basis and later determine that the more costly and time intensive trials do not support the initial value the product candidate was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

Our drug discovery efforts are centered on our small molecule discovery engine. As a company we have relatively limited experience in drug discovery generally, with targeted protein degradation and covalency as approaches to target inhibition and with computational discovery as a technology. Our future success depends, in part, on our ability to successfully use these approaches and technologies to identify promising new product candidates and eventually advance those product candidates through preclinical studies and clinical trials.

Only a limited number of product candidates using the approaches of targeted protein degradation or covalency have been approved in the United States or Europe. The data underlying the feasibility of developing therapeutic products based on these approaches remains both preliminary and limited. We have not yet succeeded

and may not succeed in advancing any product candidates developed using our small molecule discovery engine into clinical trials, demonstrating the efficacy and safety of such product candidates or obtaining regulatory approval thereafter. As a result, it is difficult to predict the time and cost of product candidate development from our small molecule discovery engine and we cannot predict whether the application of these approaches will result in the development and regulatory approval of any products. Any problems we experience in the future related to this platform or any of our related development programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any internally discovered product candidates we may develop on a timely or profitable basis, if at all.

Although we believe that our computational discovery platform has the potential to identify more promising molecules than traditional research methods and to accelerate drug discovery efforts, our focus on using our platform technology to discover and design molecules with therapeutic potential may not result in the discovery and development of commercially viable products for us. Computational discovery is a relatively new approach to drug development. As an organization, we have not yet developed any product candidates using this technology that have advanced into clinical trials and we may fail to identify potential product candidates for clinical development. Even if we are able to advance product candidates identified through our computational discovery platform into clinical trials, those trials may not be successful in demonstrating the efficacy and safety of such product candidates and, as a result, we may not be able to obtain regulatory approvals for those product candidates.

Any such failure to in-license or acquire new product candidates from third parties, or to discover new product candidates using our small molecule discovery engine or computational discovery platforms, would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

***We face risks associated with the Vant structure.***

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

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

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

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

***The global pandemic resulting from the outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including the marketing of our products and our ongoing clinical trials and preclinical studies.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, emerged. COVID-19 has since spread globally, including to the countries in which we and our business partners conduct business. Governments in affected regions have implemented, and may continue to implement or re-implement, safety precautions, including quarantines, travel restrictions, business closures, cancellations of public gatherings and other measures they deem necessary. Like many other organizations and individuals, we and our employees have taken additional steps to avoid or reduce infection, including limiting travel and implementing remote work arrangements. We will continue to actively monitor the situation and may take further actions that could alter our

business operations as may be required by national, state or local authorities, or that we determine are in the best interests of our employees and shareholders.

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

- our ability to sell and market our current and future products and, if approved, product candidates, including as a result of government- or employer-imposed remote work orders and travel and workplace visitor restrictions;
- a decrease in patient health care utilization due to quarantines, travel restrictions, work from home orders or other public health measures;
- delays or disruptions in our commercial supply chain including as a result of quarantines, travel restrictions, work from home orders or other public health measures;
- delays or difficulties in enrolling patients in our clinical trials, and the consequences of such delays or difficulties, including terminating clinical trials prematurely;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or disruptions in nonclinical experiments due to unforeseen circumstances at contract research organizations (“CROs”), and vendors along their supply chain;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA and comparable non-U.S. regulatory agencies, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials and preclinical studies, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people and increased reliance on working from home or mass transit disruptions;
- other disruptions to our business generally, including remote working activities and the implementation of new health and safety requirements for our employees; and
- waiver or suspension of patent or other intellectual property rights.

These and other factors arising from the COVID-19 pandemic, including risks relating to the resurgence or emergence of new variants of SARS-CoV-2, including variants and sub-variants thereof, the efficacy and availability of vaccines and rates of vaccination (including vaccine booster shots), the pandemic worsening in countries that are already afflicted with COVID-19 or the COVID-19 pandemic continuing to spread to additional countries or returning to countries where the pandemic has been partially contained, could further adversely impact our ability to market our products and conduct clinical trials and other business activities, and could have a material adverse impact on our operations and financial condition and results.



To the extent the COVID-19 pandemic adversely affects our business, operations and financial results, it may also have the effect of heightening many of the other risks described elsewhere, such as those relating to our clinical development operations, the supply chain for our ongoing and planned clinical trials and our ability to seek and receive regulatory approvals for our product candidates.

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

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

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

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

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

We have historically and may in the future enter into various types of corporate transactions, including acquisitions, strategic partnerships, alliances or collaborations and licensing transactions. These past and future transactions pose certain risks to our business, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our or our subsidiaries' equity securities which would result in dilution to existing shareholders;
- assimilation of operations, intellectual property and products, including difficulties associated with integrating new personnel;
- diversion of management time and focus away from operating our business;
- the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the counterparty to any such transaction;

- our inability to eventually generate revenue from acquired technology or products or product candidates sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs;
- litigation or other claims, including claims from terminated employees, customers, former shareholders or other third parties.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses, any of which could have a material adverse effect on our business, prospects, financial condition or results of operations.

Further, any such transactions may be complex, time-consuming and expensive to execute and may be subject to regulatory requirements that could impact our business. There can be no guarantee that we will be able to successfully consummate such acquisitions or other transactions, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket costs.

If any acquisitions or other transactions are not completed for any reason, we may incur significant costs and the market price of our Common Shares may decline. In addition, even if an acquisition or other transaction is consummated, the integration of the acquired business, product or other assets into our Company may be complex and time-consuming, and we may not achieve the anticipated benefits, cost-savings or growth opportunities we expect. Potential difficulties that may be encountered in the integration process include the following: integrating personnel, operations and systems; coordinating geographically dispersed organizations; distracting management and employees from current operations; maintaining the existing business relationships of the acquired company; and managing inefficiencies associated with integrating the operations of the Company and the acquired business, product or other assets. For biopharmaceutical businesses we have acquired or may acquire in the future, or alliances or joint ventures in the biopharmaceutical industry, we may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, alliance or partnership, we will achieve the expected synergies to justify the transaction.

Our failure to address these risks or other problems encountered in connection with past or future acquisitions, partnerships or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, incur unanticipated liabilities and harm our business generally. There is also a risk that current or future acquisitions will result in the shareholder litigation, incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

***If we obtain a controlling interest in additional companies in the future, it could adversely affect our operating results and the value of our Common Shares, thereby disrupting our business.***

As part of our strategy, we expect to form and invest in additional wholly-owned and majority-owned subsidiaries. Investments in our existing and any future subsidiaries involve numerous risks, including, but not necessarily limited to, risks related to:

- conducting research and development activities in new therapeutic areas or treatment approaches in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- actual or potential conflicts among new and existing Vants to the extent they have overlapping or competing areas of focus or pipeline products;

- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

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

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

#### ***Risks Related to the Development of Our Products and Product Candidates***

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

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

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

The FDA or other regulatory authorities may also not agree with the scope of our proposed investigational plan. For example, they may find that our proposed development program is not sufficient to support a marketing

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

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

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

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

- failure to manufacture or release sufficient quantities of our product candidates or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

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

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

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

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

***Our approach to the discovery and development of product candidates from our small molecule discovery engine is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates from this platform.***

Treating diseases using targeted protein degradation, covalency and similar approach is novel and unproven. Our future success depends in part on the successful development of these new therapeutic approaches. Very few small molecule product candidates using targeted protein degradation or covalency have been tested in humans. Only a limited number of product candidates using targeted protein degradation or covalency have been approved in the United States or Europe and the data underlying the feasibility of developing these types of therapeutic products remains both preliminary and limited. If any adverse learnings are made by other developers of protein degraders or covalent inhibitors, development of these product candidates could be materially impacted, which could in turn adversely impact our financial condition and future growth.

The scientific research that forms the basis of our efforts to develop product candidates from our small molecule discovery engine is ongoing and the scientific evidence to support the feasibility of developing these treatments is both preliminary and limited. In addition, we may be unable to replicate the scientific evidence supporting these product candidates observed by our academic collaborators in commercial laboratories.

Further, certain cancer patients have shown inherent primary resistance to approved drugs that inhibit disease-causing proteins and other patients have developed acquired secondary resistance to these inhibitors. Although we believe our product candidates may have the ability to degrade the specific mutations that confer resistance to currently marketed inhibitors of disease-causing enzymes, any inherent primary or acquired secondary resistance to our product candidates in patients, or if the research proves to be contradicted, would prevent or diminish their clinical benefit.

We have not yet completed IND-enabling work for, or initiated a clinical trial of, any product candidate associated with our small molecule discovery engine and we have not yet assessed the safety of any of these product candidates in humans. Although some of our product candidates have produced observable results in animal studies, there is a limited safety data set for their effects in animals. In addition, these product candidates may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result, there could be adverse effects from treatment with any of our current or future products or product candidates that we cannot predict at this time.

Additionally, the regulatory approval process for novel product candidates such as those associated with our small molecule discovery engine is uncertain and can be more expensive and take longer than for other, better-known or extensively studied classes of product candidates. Although other companies are also developing therapeutics based on targeted protein degradation and similar approaches, only a limited number of product candidates of this type have been approved in the United States or Europe. As a result, it is difficult for us to predict the time and cost of developing our product candidates and we cannot predict whether any of our product candidates will receive marketing approval or achieve commercial acceptance. Any development problems we experience in the future related to our small molecule discovery engine or any of our related research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, as well as from commercializing any product candidates we may develop on a timely or profitable basis, if at all.

***Certain of our products and product candidates are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.***

The manufacturing processes our CMOs use to produce our products and product candidates are complex, novel and, in the case of our product candidates, have not necessarily been validated for commercial use. Several

factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers.

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

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

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

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

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

Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our products and product candidates, including batoclimab, which targets certain rare autoimmune indications, there are limited patient

pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. In addition, for certain of our early-stage development programs, there may be a limited number of sites where it is feasible to run clinical trials, making such programs particularly susceptible to delays caused by issues at those sites.

Furthermore, any negative results or new safety signals we may report in clinical trials of our products or product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting or to resume enrolling patients once a paused clinical trial has been resumed. For example, in February 2021, our subsidiary, Immunovant, voluntarily paused dosing in its clinical trials for batoclimab globally due to elevated total cholesterol and low-density lipoprotein (“LDL”) levels observed in some patients treated with batoclimab, resulting in a delay in Immunovant’s development of batoclimab. In current and future trials of batoclimab, it may be more difficult for Immunovant to recruit and retain patients for such clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our products and product candidates, or could render further development impracticable. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Any such delays in our current or future clinical trials could have a material adverse impact on our operations and financial condition and results.

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

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

As previously disclosed, our subsidiary, Immunovant, voluntarily paused dosing in its early phase clinical studies to evaluate batoclimab-induced elevations in total cholesterol and LDL levels observed in some trial subjects. In December 2021, Immunovant achieved alignment with the FDA Division of Neurology 1 to move forward with its pivotal study of batoclimab as treatment for myasthenia gravis (“MG”) and initiated its Phase 3 trial in MG in June 2022. Following expected discussions with the FDA Division of Hematology, Immunovant intends to initiate a randomized, placebo-controlled study of batoclimab as treatment for warm autoimmune hemolytic anemia (“WAIHA”). In addition, Immunovant recently achieved alignment with the FDA Division of Ophthalmology to move forward in thyroid eye disease (“TED”). It plans to initiate its pivotal program for batoclimab in TED in calendar year 2022. Immunovant continues to evaluate potential new indications for batoclimab and plans to announce two new indications by August 2022. Immunovant expects one of its three indications beyond MG and TED to be initiated as a pivotal study in calendar year 2022. Failure to successfully



complete or replicate clinical trials of batoclimab and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market batoclimab would significantly harm our business.

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

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

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

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

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

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

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

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

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

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

approval for, or successfully commercialize any product or product candidate that we develop. As a result, our financial results and the commercial prospects for any product or product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

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

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

Third-party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third-party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third-party manufacturers or third parties in the supply chain for materials used in the production of our products or product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our products for commercialization and products or product candidates for our preclinical studies, clinical trials and research and development activities. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, for either commercialization or an ongoing clinical trial, due to the need to replace a third-party manufacturer or otherwise, could considerably delay marketing efforts for the product in question or the completion of clinical trials, product testing and potential regulatory approval of the product candidate in question. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our products or product candidates, the commercial launch of our products or product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products or product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our products or product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involve committing substantial financial resources to current or future products or product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the United States on foreign supply chains and manufacturing. While we are still assessing these developments, they could impact our selection and utilization of CMOs, vendors and other suppliers and could have a material adverse impact on our business, financial condition and results of operations.

The facilities used by our contract manufacturers to manufacture our products and product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or other similar

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

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

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

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

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

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

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

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

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a supplemental NDA or similar regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. In some cases, the technical skills required to manufacture our products and product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product or product candidate according to the specifications previously

submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Accordingly, switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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

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

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

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

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

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

- the FDA or other relevant regulatory authorities may not find the data from nonclinical, preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks;
- the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, preclinical studies or clinical trials or may require additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites;
- if an NDA, BLA or a similar application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authorities, as the case may be, require, as a condition of approval, additional nonclinical, preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy (“REMS”) or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or patient registries for product candidates;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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

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

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down the product candidate development and approval process and delay or potentially

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

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

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

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

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

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

Adverse events caused by or associated with our products and product candidates have caused us and could, in the future, cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects arising from, or those perceived to arise from, our product candidates or those from other companies targeting similar diseases, could also affect patient recruitment or the ability of enrolled patients to complete their participation in our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. For example, as previously disclosed, our subsidiary Immunovant voluntarily paused dosing in early phase clinical studies for batoclimab globally to evaluate batoclimab-induced elevations in total cholesterol and LDL levels



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

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

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

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

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

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable non-U.S. regulatory authorities, that such product candidate is safe and effective and, as applicable, pure and potent for its intended use. Results from nonclinical studies and clinical trials can be

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

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

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

Seeking regulatory approval outside of the United States could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The regulatory approval process outside of the United States may include all of the risks associated with obtaining FDA approval. Other than VTAMA, we do not have any products or product candidates approved for sale in any jurisdiction, including international markets, and we do not have significant experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

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

We have one product, VTAMA, approved by the FDA for the treatment of plaque psoriasis in adults in the U.S. Any product or product candidate for which we obtain marketing approval will be subject to extensive and

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

The FDA and other relevant regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs, result in regulatory enforcement, or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and that promotional and advertising materials and communications are truthful and non-misleading. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications and if we do not market our products or product candidates for their approved indications or in a manner which regulators believe to be truthful and non-misleading, we may be subject to enforcement action. Moreover, in the EU we will be prohibited from promoting prescription-only medicinal products to individuals who are not healthcare professionals. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable laws and regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non-U.S. regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in other jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products or product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may negatively impact our business and the price of our Common Shares and may yield various results, including:

- restrictions on the manufacture of such products or product candidates;
- restrictions on the labeling or marketing of such products or product candidates, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the United States);
- Warning or Untitled Letters or similar communications from other relevant regulatory authorities;

- withdrawal of the product or product candidates from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products or product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension, variation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products or product candidates;
- seizure of our products or product candidates; or
- lawsuits, injunctions or the imposition of civil or criminal penalties.

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

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

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

- monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good applicable practice (“GxP”) (e.g., GCP, GLP and GMP regulated) products;
- monitoring and providing oversight of all GxP suppliers (e.g., contract development manufacturing organizations and CROs);
- establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and
- cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality.

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

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

We have sought, or may in the future seek, Breakthrough Therapy Designation, Fast Track Designation, Regenerative Medicine Advanced Therapy Designation or Orphan Drug Designation for certain of our product candidates.

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

Recently, there has been heightened scrutiny of the accelerated approval pathway, with some stakeholders advocating for reform. The U.S. Department of Health and Human Services (“HHS”) Office of Inspector General has initiated an assessment of how the FDA implements the accelerated approval pathway. In addition, members of Congress have introduced proposed legislation to revise the statutory accelerated approval pathway, including with respect to FDA’s ability to rapidly withdraw products and indications for which effectiveness is not confirmed in post-marketing studies. At this time, it is not clear what impact, if any, these developments may have on the statutory accelerated approval pathway or our business, financial condition results of operations, or prospects.

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

Regulatory authorities in some jurisdictions, including the United States and the European Economic Area (the “EEA”), may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals annually in the United States or for which there is no reasonable expectation that costs of research and development of the drug for the disease or condition can be recovered by sales of the drug in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same orphan indication for that time period. In the United States, in order for a product to receive orphan drug exclusivity, FDA must not have previously approved a drug considered the same drug for the same orphan indication, or the subsequent drug must be shown to be clinically superior to such a previously approved same drug. The applicable period of marketing exclusivity is seven years in the United States. A similar data exclusivity scheme exists in the EEA. The European Commission, on the basis of a scientific opinion by the EMA’s Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more

than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, Orphan Drug Designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to certain benefits, such as scientific assistance (protocol assistance), financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission, EMA and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the “normal” data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company’s preclinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic drug can be marketed for ten years from the first approval of the innovator drug in the EEA; the innovator drug may qualify for an extra year’s protection. This additional one year of marketing exclusivity may be obtained where the innovator company is granted a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic company can only market their product after 11 years from the first grant of the innovator company’s marketing authorization for the product in the EEA.

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

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

If we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the European Commission can subsequently approve the same drug for a different condition or the same condition if the FDA or the EMA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EEA, a marketing authorization may also be granted, for the same therapeutic indication, to a competitor with a similar medicinal product during the exclusivity period if we are unable to supply sufficient quantities of the medicinal product for which we received marketing authorization. Upcoming legislative reforms in the EU may result in a reduction of market exclusivity periods for orphan medicinal products, changes to the concept of unmet medical need and/or imposition of additional requirements for grant of such exclusivity.

Moreover, a recent Eleventh Circuit decision in *Catalyst Pharmaceuticals, Inc. vs. FDA* regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug’s orphan designation has the potential to significantly broaden the scope of orphan drug exclusivity for such products. Depending on how broadly FDA applies the Catalyst decision, it could fundamentally change how companies rely on, or seek to work around, orphan drug exclusivity. Legislation has been introduced that may reverse the Catalyst decision, and may be enacted as part of the reauthorization of user fees later this year.

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

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

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

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act" or "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway under section 351(k) of the Public Health Service Act ("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 PHS Act 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. While the full impact of these provisions is unclear at this time, its provisions do have the potential to facilitate the development and future approval of biosimilar versions of our products, introducing biosimilar competition that could have a material adverse impact on our business, financial condition and results of operations.

Whether approval of a biological product qualifies for reference product exclusivity turns on whether FDA consider the approval a "first licensure." Not every licensure of a biological product is considered a "first licensure" that gives rise to its own exclusivity period. We believe that our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, 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 not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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

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

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product or, if approved, product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.



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

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

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of a product or, if approved, product candidate, we may be forced to delay commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring a product or, if approved, product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to our products or product candidate or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

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

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

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

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration,

directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program (such as Medicare and Medicaid). The term “remuneration” has been broadly interpreted by the federal government to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain activities from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to \$100,000 for each violation. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal false claims laws, including the False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim; or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties currently ranging from \$11,803 to \$23,607 for each false claim or statement for penalties assessed after December 13, 2021, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses and most healthcare providers (collectively, “covered entities”), and such covered entities’ “business associates,” defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of the covered entity;
- various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level impose obligations with respect to safeguarding the privacy, security, and cross-border transmission of personal data and health information;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded

from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

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

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

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

The United States and many other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities for our products and affect our ability to profitably sell our products, and prevent or delay marketing approval of our current and any future product candidates. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs for pharmaceuticals. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, with unpredictable and uncertain results. Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will after a pause in early 2022 remain in effect through 2031 unless additional Congressional action is taken. Pursuant to the CARES Act and subsequent legislation, these reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of the sequester. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and reform government program reimbursement methodologies for drugs. Current Congressional proposals include direct price negotiation by Medicare in Medicare Parts B and D, international reference pricing for certain Medicare drugs, and inflationary rebates on Part B and Part D drugs whose prices

increase above a certain amount, and Part D drug benefit redesign. At the federal level, the former Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS implemented several of these provisions to date. In May 2019, Centers for Medicare and Medicaid Services (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 adopted a six-year moratorium on implementation or enforcement of the rule as a part of the Infrastructure Investment and Jobs Act. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Moreover, on November 19, 2021, the House passed the Build Back Better Act, which among other provisions, would permit the Secretary of HHS to negotiate certain high-expenditure Part D drugs, impose inflationary rebates for Part D drugs, and redesign the Part D benefit. The Senate Finance Committee introduced a modified version of the legislation on December 11, 2021, but negotiations have since stalled. Although the House and Senate versions of this legislation would grant certain exceptions for “small biotech drugs” and “specified small manufacturers,” if passed, we cannot predict how these exceptions would be implemented and their impact on Roivant.

Moreover, upcoming legislative and policy changes in the EU, some of which may materialize as early as 2022, are aimed at increasing accessibility and affordability of medicinal products, as well as at increased cooperation between the EU Member States. Such initiatives may further impact the price and reimbursement status of our products in the future.

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

- the demand for our products and, if approved, product candidates;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for our products and, if approved, product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent

us from being able to generate sufficient revenue, attain profitability or successfully commercialize our products and, if approved, product candidates.

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

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

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

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

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

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

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

We may face competition in the United States for our products and, if approved, product candidates, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act (“MMA”) contains provisions that may change U.S. importation laws and expand pharmacists’ and wholesalers’ ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public’s health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U.S. District Court for the District of Columbia, requesting injunctive relief to prevent implementation of the rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for “best price” or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code (“NDC”), for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for our products and, if approved, product candidates. The regulatory and market implications of the final rule and guidance are

unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for our products and, if approved, product candidates and adversely affect our future revenues and prospects for profitability.

#### ***Other Risks Related to Our Business and Industry***

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

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

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

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

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

In connection with our continued growth, we expect to hire, either directly or through our current or future affiliates, additional employees for our managerial, finance and accounting, clinical, scientific and engineering, regulatory, operational, manufacturing, sales and marketing teams. We may have difficulties in connection with



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

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

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

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

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

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

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience difficulties in commercializing our products and, if approved, product candidates and our business, results of operations, financial condition and cash flows could be adversely affected.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our products and, if approved, product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

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

- Roflumilast, a PDE4 inhibitor, a potential competitor to VTAMA, which in May 2022 was approved by the FDA for the treatment of plaque psoriasis in adults in the U.S. under the brand name VTAMA cream and which is also in development by Dermavant for the topical treatment of atopic dermatitis;
- Ruxolitinib, a topical Janus kinase inhibitor, a potential competitor to VTAMA, in development by Dermavant for the topical treatment of atopic dermatitis;
- Teprotumumab, an insulin-like growth factor-1 receptor inhibitor, which in January 2020 was approved by the FDA for the treatment of TED, a potential competitor to batoclimab, in development by Immunovant for the treatment of TED and other autoimmune diseases;
- VYVGART™ (efgartigimod alfa-fcab), a neonatal Fc receptor blocker, which in December 2021 was approved by the FDA for the treatment of MG in adults who test positive for the anti-acetylcholine

receptor antibody, a potential competitor to batoclimab, in development by Immunovant for the treatment of MG and other autoimmune diseases;

- Efgartigimod, an anti-FcRn antibody fragment, nipocalimab, an anti-FcRn antibody, Zilucoplan, a peptide inhibitor of C5, and inebilizumab, a CD19-targeted humanized monoclonal antibody, all potential competitors to batoclimab, in development by Immunovant for the treatment of MG and other autoimmune diseases;
- Ultomiris (Ravulizumab-cwvz), a complement inhibitor, which in April 2022 was approved by the FDA for the treatment of generalized MG in adults who are anti-acetylcholine receptor antibody-positive, a potential competitor to batoclimab, in development by Immunovant for the treatment of MG and other autoimmune diseases;
- Rituximab, a monoclonal antibody, a potential competitor to batoclimab, in development by Immunovant for the treatment of TED, WAIHA and other autoimmune diseases;
- Fostamatinib, a syk inhibitor, ibrutinib, a BTK inhibitor, and ANX005, an antibody inhibitor, all potential competitors to batoclimab, in development by Immunovant for the treatment of WAIHA and other autoimmune diseases; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We cannot anticipate all possible types of security threats and we cannot guarantee that our data protection efforts and our investments in information technology will prevent significant breakdowns, data leakages, security breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If any of the aforementioned security events were to occur, it could result in a material disruption of our commercialization efforts, drug development programs and other business operations. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we rely on third parties to supply components for and to manufacture our product candidates and to

conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and reputational damage and the commercialization efforts for our products and further development of any product candidate could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks.

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

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

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

In addition, many U.S. states in which we operate have laws that protect the privacy and security of personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act (the “CMIA”), a statute similar to HIPAA that expressly applies to pharmaceutical companies as well as companies that provide certain technologies for processing personal health information, imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA 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, with limited exceptions, and requires security measures to protect such information. The CMIA authorizes administrative fines and civil penalties of up to \$25,000 for willful violations and up to \$250,000 if the violation is for purposes of financial gain, as well as criminal fines. In addition, another more recently enacted California law, the California Consumer Privacy Act of 2018 (the “CCPA”), requires us to provide notice to California residents regarding the personal information we collect, use and share and to honor such residents’ privacy rights, including the right to opt-out of the sale of their personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data security breaches that result in the compromise of highly sensitive personal information, which may increase the likelihood of, and risks associated with, data breach litigation. As of January 1, 2023, the CCPA regime will become more complex and enforcement may increase, pursuant to amendments adopted pursuant to the California Privacy Rights Act (the “CPRA”), a ballot initiative that passed in November 2020. The CPRA, among other things, created a new state

agency, the California Privacy Protection Agency, to implement and enforce the CCPA and the CPRA. The CPRA also gave California residents new rights to limit uses and disclosures of “sensitive personal information,” including personal health information, and the right to opt out of the sharing of personal information for targeted online advertising. California’s aggressive steps to protect consumer privacy have been followed by similar actions in other states, including Virginia, Colorado, Utah and Connecticut, all of which have enacted CCPA/CPRA-like laws to provide their respective residents with similar rights. New legislation anticipated to be enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. The effects on our business of this growing body of privacy and data protection laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Outside of the United States, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in EEA, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the “GDPR”). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on controllers, including *inter alia*: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with data protection rights of data subjects; and (iv) reporting of certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible). The GDPR also prohibits the transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. The EU-US Privacy Shield, 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”).

The CJEU upheld the validity of standard contractual clauses (“SCCs”) as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA and the U.K., need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. Due to potential legal challenges, it remains to be seen whether SCCs will remain a valid legal mechanism and whether additional means for lawful data transfers will become available. In June 2021, the European Commission adopted new SCCs that are designed to be a mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, the SCCs are a valid mechanism to transfer personal information outside of the EEA. The SCCs, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. The new SCCs may increase the legal risks and liabilities under European privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs, any transfers by us or our vendors of personal information from Europe may not comply with European data protection law, which may increase our exposure to the GDPR’s heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of E.U. personal information outside of the E.U. (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products. Moreover, the competent authorities and courts in a number of EU Member States increasingly scrutinize and question the GDPR compliance of processing of personal data by US-based entities or entities with links to US-based entities, independently of whether personal data is actually transferred outside the EEA. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by customers and data subjects. European data protection authorities may

interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA. In June 2021, the CJEU issued a ruling that expanded the scope of the “one stop shop” under the GDPR. According to the ruling, the competent authorities of EU Member States may, under certain strict conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross-border processing activities, even such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority.

Further, as of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and EU (*i.e.*, following the United Kingdom’s exit from the EU—otherwise known as Brexit), data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the United Kingdom’s data protection framework, enabling data transfers from EU member states to the United Kingdom to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data.

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

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



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

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

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

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

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

product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

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

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

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

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

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

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

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

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

We are centrally managed and controlled in the United Kingdom. The United Kingdom formally exited the EU, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the United Kingdom entered a transition period (the "Transition Period"), during which it continued to follow all EU rules. The Transition Period ended on December 31, 2020. A trade and cooperation agreement which outlines the trading relationship between the U.K. and E.U. now that the transition period has concluded, applied provisionally from January 1, 2021 and formally entered into force on May 1, 2021.

There is considerable uncertainty resulting from a lack of precedent and the complexity of the United Kingdom and the EU's intertwined legal regimes as to how Brexit (following the Transition Period) will impact

the life sciences industry in the UK and Europe, including our company, including with respect to ongoing or future clinical trials. The impact will largely depend on the model and means by which the United Kingdom's relationship with the EU is governed post-Brexit and the extent to which the United Kingdom chooses to further diverge from the EU regulatory framework. For example, following the Transition Period, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorizations and our products will therefore require a separate marketing authorization to allow us to market such products in Great Britain. By way of additional example, the EU Clinical Trials Regulations which govern the conduct of clinical trials in the E.U. entered into application in January 2022 and consequently do not apply in the U.K. It is unclear as to whether the relevant authorities in the EU and the United Kingdom are adequately prepared for the additional administrative burden caused by Brexit. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from or delay us commercializing our products and, if approved, product candidates in the United Kingdom and/or the EEA and restrict our ability to generate revenue and achieve and sustain profitability. In the short term, following the expiry of the Transition Period there have been disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that, if continued, may delay time-sensitive shipments and may negatively impact our product supply chain. Further, under current plans, orphan designation in the United Kingdom (or Great Britain, depending on whether there is a prior centralized marketing authorization in the EEA) following Brexit is to be based on the prevalence of the condition in Great Britain as opposed to the current position where prevalence in the EU is the determinant. It is therefore possible that conditions that are currently designated as orphan conditions in the United Kingdom will no longer be and that conditions are not currently designated as orphan conditions in the European Union will be designated as such in the United Kingdom.

If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EEA for our products and product candidates, which could significantly and materially harm our business. There is a degree of uncertainty regarding the overall impact that Brexit will have on (i) the marketing of pharmaceutical products, (ii) the process to obtain regulatory approval in the United Kingdom for product candidates or (iii) the award of exclusivities that are normally part of the EU legal framework (for instance Supplementary Protection Certificates, Pediatric Extensions or Orphan exclusivity).

Brexit may also result in a reduction of funding to the EMA once the United Kingdom no longer makes financial contributions to European institutions, such as the EMA. If funding to the EMA is so reduced, it could create delays in the EMA issuing regulatory approvals for our products and product candidates and, accordingly, have a material adverse effect on our business, financial condition, results of operations or prospects.

In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our products or product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the EU for our products and product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business.

As a result of Brexit, other EU Member States may seek to conduct referenda with respect to their continuing membership with the EU. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the EU will have and how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

## ***Risks Related to Our Intellectual Property***

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

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

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

The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future products or product candidates in the United States or in other countries. Our pending patent applications at the Patent Cooperation Treaty (the "PCT") are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority

date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. For example, any issued patents might not cover the pharmaceutical composition of the product or product candidate that is ultimately commercialized. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may ultimately obtain. Even if patents do successfully issue and even if such patents cover our current and future products and product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowly construed, invalidated, or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or product candidates or limit the length of terms of patent protection we may have for our products, product candidates and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing products or product candidates, or practicing our own patented technology, or impose a substantial royalty burden to do so. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products or, if approved, product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products or, if approved, product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our products, product candidates or other technologies, competitors and other third parties could market products or product candidates and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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

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

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

products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We are currently and may in the future be subject to third-party pre-issuance submissions of prior art to the USPTO or its equivalents and we or our licensors have in the past, and may in the future, become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the U.S. or in other jurisdictions challenging our patent rights or the patent rights of others. A third-party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. For example, three U.S. patents (U.S. Patent Nos. 8,058,069, 9,364,435 and 9,404,127) relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH, as assignee of Genevant Sciences Ltd. (“Genevant”), exclusively licensed from Arbutus Biopharma Corp. (“Arbutus”) were the subject of *inter partes* review proceedings brought by Moderna Therapeutics, Inc. (“Moderna”) before the Patent Trial and Appeal Board of the USPTO (“PTAB”). The PTAB upheld all claims of U.S. Patent No. 8,058,069, invalidated some of the claims of U.S. Patent No. 9,364,435 and invalidated all claims of U.S. Patent No. 9,404,127. The United States Court of Appeals for the Federal Circuit (the “Federal Circuit”) heard oral arguments with respect to U.S. Patent Nos. 8,058,069 and 9,364,435 in October 2021. On December 1, 2021, the Federal Circuit issued decisions in both proceedings. The Federal Circuit affirmed the PTAB’s decision that upheld all claims of U.S. Patent 8,058,069. The Federal Circuit affirmed the PTAB’s decision invalidating certain claims of U.S. Patent 9,364,435 but dismissed Moderna’s appeal with respect to those claims that the PTAB upheld for lack of standing. The Federal Circuit vacated and remanded the PTAB’s decision on U.S. Patent No. 9,494,127. The PTAB’s decision with respect to U.S. Patent No. 9,494,127 had been held in administrative abeyance pending a review following a recent Supreme Court ruling in an unrelated case. The matter is now pending before the Federal Circuit and briefing is complete. We expect that the Federal Circuit will schedule oral arguments to take place later this calendar year. Additionally, one European patent (EU patent no. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licensed from Arbutus is the subject of an opposition proceeding brought by Merck Sharp & Dohme Corporation and Moderna at the European Patent Office Opposition Division. Genevant may commence litigation at any time to enforce its patent rights against infringers.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete

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

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product or product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, are limited. Even if patents covering products or product candidates are obtained, once the patent life has expired, we may be open to competition from other products or product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new products and product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, the patent covering the use of VTAMA as an active ingredient to treat psoriasis and atopic dermatitis, but not limited to any formulation, expired in December 2020. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our products and product candidates.

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

Composition-of-matter patents on the active pharmaceutical ingredient (“API”) in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture



or formulation of the API used. While we generally seek composition of matter patents for our products and product candidates, such patents may not be available for all of our products and product candidates. For example, we do not own or have a license to any issued composition of matter patents in the United States or any other jurisdiction with respect to VTAMA. Instead, we rely on an issued U.S. patent claiming topical formulations of VTAMA, including the formulation studied in Phase 3 trials and approved by the FDA, and an issued U.S. patent covering methods of using the patented topical formulations to treat inflammatory diseases, including psoriasis and atopic dermatitis. The formulation and method-of-use patents have natural expiration dates in 2036. We additionally rely on a drug substance (“DS”) patent covering the high purity commercial crystal form of the DS, the commercial DS synthesis and several novel intermediates that are formed in the synthesis, which has a natural expiration date in 2038.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third-party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

Our owned and licensed patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own or license with respect to our products and product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products and, if approved, product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of product candidates, one or more of our U.S. patents may be eligible for a limited patent term extension (“PTE”) under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an

extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval for a given product or product candidate.

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

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

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

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

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

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

which could harm our business, financial condition, results of operations and prospects. For example, disputes may arise with respect to our current or future licensing agreement include disputes relating to:

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

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

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

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

Furthermore, certain of our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with rights to use such intellectual property

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

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

Our commercial success depends in part on our avoidance of infringement, misappropriation and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Our competitors or other third parties may assert infringement claims against us, alleging that our products or product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review, and post-grant review before the USPTO, as well as oppositions and similar processes in other jurisdictions. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility, the risk increases that our products, product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products or product candidates. We could also be required to pay damages, which could be significant, including treble damages and attorneys’ fees if we are found to have willfully infringed such patents.

Additionally, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover any of our products or product candidates, the holders of any such patents may be able to block our ability to commercialize such products or, if approved, product candidates, unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product or, if approved, product candidate, unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Claims that we have

misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could be time-consuming and divert the attention of senior management.

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

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

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

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

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

and future products and product candidates, or the use thereof, provided such pending patent applications result in issued patents. Our ability to develop and market our current and future products and product candidate can be adversely affected in jurisdictions where such patents are issued.

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

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

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

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

In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court and if any such suits, including the Moderna Action and the Acuitas Action, will ultimately be resolved successfully. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives, or could put our patent applications at risk of not issuing. The initiation of a claim against a

third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or non-statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future products or product candidates. Such a loss of patent protection could harm our business. Additionally, any adverse outcome could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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

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

when the patent is assigned to a subsidiary, which is not the entity that is or would be commercializing a potentially competitive product or service. In such a circumstance, such third-party may be able to compete with us or our subsidiaries, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

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

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." For example, the research resulting in certain of our acquired or in-licensed patent rights and technology for certain products or product candidates was funded in part by the U.S. federal government. As a result, the federal government may have certain rights to such patent rights and technology, which include march-in rights. If the federal government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The federal government's rights may also permit it to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The federal government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. Further, the recipient of U.S. government funding is required to comply with



certain other requirements, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. The U.S. government has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, our rights in such inventions may be subject to certain requirements to manufacture products or product candidates embodying such inventions in the United States. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times or be able to rectify any lapse in compliance with these requirements. Any exercise by the government of any of the foregoing rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

For example, our three issued U.S. patents covering VTAMA may not provide adequate protection from competitive products developed by 505(b)(1) NDA, 505(b)(2) NDA or 505(j) ANDA applicants containing paragraph IV certifications if such applicants are able to design around the three patents. One or more competitors may circumvent these patents by filing a marketing application with the FDA under Sections 505(b)(2) or 505(j) of the Federal Food, Drug and Cosmetic Act containing a paragraph IV certification for a competitive product containing the active moiety in VTAMA and successfully challenging the validity of the three patents or successfully designing around the three patents. Any successful challenge against the three patents and/or designing around one or more of the patents could result in a generic version of VTAMA being commercialized before the expiration of the three patents. If the three patents are successfully challenged or designed around, our business, results of operations, financial condition and prospects would be harmed.

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products and product candidates, which could make it difficult for us to stop the

infringement of our patents or marketing of competing products or product candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain

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

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

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

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

Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties, controls on the origin of the software or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our solutions. By the terms of certain open source licenses, if

portions of our proprietary software are determined to be subject to an open source license or if we combine our proprietary software with open source software in a certain manner, we could be required to release the source code of our proprietary software and to make our proprietary software available under open source licenses, each of which could reduce or eliminate the effectiveness of our computational discovery efforts. We may also face claims alleging noncompliance with open source license terms or misappropriation or other violation of open source technology. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

We employ individuals who were previously employed at universities or other software, biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to not use the confidential information of their former employer, we may be subject to claims that we or our employees, consultants, independent contractors or other third parties have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our owned or licensed patents or patent applications. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, could limit the duration of the patent protection covering our technology, products and product candidates and could result in our inability to develop, manufacture or commercialize our products and product candidates without infringing third-party patent rights. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our current or future products and product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may harm our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would harm our business, results of operations and financial condition.

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

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

In addition, while it is our policy to require our employees, contractors and other third parties who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to

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

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

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

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

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

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

The in-licensing and acquisition of third-party intellectual property rights for any future product candidate is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash

resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

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

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

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

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

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

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

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

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

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

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

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

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

If our performance does not meet market expectations, the price of our Common Shares may decline. In addition, even if an active market for our Common Shares develops and continues, the trading price of our Common Shares could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Prior to the Business Combination, there was not a public market for our Common Shares, and trading in our Common Shares was not active. Any of the factors listed below could have a material adverse effect on the price of our Common Shares.



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

- actual or anticipated fluctuations in our quarterly and annual financial results or the quarterly and annual financial results of companies perceived to be similar to it;
- changes in the market's expectations about operating results;
- our operating results failing to meet market expectations in a particular period;
- a Vant's operating results failing to meet market expectations in a particular period, which could impact the market prices of shares of a public Vant or the valuation of a private Vant, and in turn adversely impact the trading price of our Common Shares;
- receipt of marketing approval for a product or product candidate in one or more jurisdictions, or the failure to receive such marketing approval;
- the results of clinical trials or preclinical studies conducted by us and the Vants;
- changes in financial estimates and recommendations by securities analysts concerning us, the Vants or the biopharmaceutical industry and market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- changes in laws and regulations affecting our and the Vants' businesses;
- the outcome of litigation or other claims or proceedings, including governmental and regulatory proceedings, against us or the Vants;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- the volume of our Common Shares available for public sale and the relatively limited free float of our Common Shares;
- any significant change in our board of directors or management;
- sales of substantial amounts of our Common Shares by directors, executive officers or significant shareholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

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

***Our warrant agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our Warrants, which could limit the ability of warrant holders to obtain a favorable judicial forum for disputes with our company.***

Our warrant agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the warrant agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern

District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the warrant agreement do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our Warrants shall be deemed to have notice of and to have consented to the forum provisions in our warrant agreement. If any action, the subject matter of which is within the scope the forum provisions of the warrant agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (a “foreign action”) in the name of any holder of our Warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an “enforcement action”) and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder’s counsel in the foreign action as agent for such warrant holder.

This choice-of-forum provision may limit a warrant holder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with our company, which may discourage such lawsuits. Warrant holders who do bring a claim in a court of the State of New York or the United States District Court for the Southern District of New York could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of New York. Alternatively, if a court were to find this provision of our warrant agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

***We may amend the terms of the Warrants in a manner that may be adverse to holders of Public Warrants with the approval by the holders of at least 50% of the then outstanding Public Warrants. As a result, the exercise price of your Warrants could be increased, the exercise period could be shortened and the number of shares purchasable upon exercise of a warrant could be decreased, all without your approval.***

Our Warrants were initially issued by MAAC in registered form under a warrant agreement between Continental Stock Transfer & Trust Company (“CST”), as warrant agent. In connection with the consummation of the Business Combination, American Stock Transfer & Trust Company assumed CST’s responsibilities as warrant agent under the warrant agreement.

The warrant agreement provides that the terms of the Warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correct any mistake or defective provision (ii) amending the provisions relating to cash dividends on common stock as contemplated by and in accordance with the warrant agreement or (iii) adding or changing any provisions with respect to matters or questions arising under the warrant agreement as the parties to the warrant agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the Warrants, provided that the approval by the holders of at least 50% of the then-outstanding Public Warrants is required to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Warrants, convert the Warrants into cash, shorten the exercise period or decrease the number of our Common Shares purchasable upon exercise of a warrant.

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

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

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

***Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.***

As a public company, we are required to provide management's attestation on internal controls as required under Section 404(a) of the Sarbanes-Oxley Act. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us as a privately-held company. If we are not successful in implementing the additional requirements of Section 404(a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

Failure to properly implement internal controls on a timely basis may lead to the identification of one or more material weaknesses or control deficiencies in the future, which may prevent us from being able to report our financial results accurately on a timely basis or help prevent fraud, and could cause our reported financial results to be materially misstated and result in the loss of investor confidence or delisting and cause the market price of our Common Shares to decline. If we have material weaknesses in the future, it could affect the financial results that we report or create a perception that those financial results do not fairly state our financial position or results of operations. Either of those events could have an adverse effect on the value of our Common Shares.

Further, even if we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our results of operations or cause us to fail to meet our future reporting obligations.

***We may redeem your unexpired Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your Warrants worthless.***

We have the ability to redeem outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the last reported sales price of our Common Shares is equal to or exceeds \$18.00 per share (as adjusted for share sub divisions, share capitalizations, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day

period ending on the third trading day prior to the date they send the notice of redemption to the warrant holders. If and when the Warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares upon exercise of the Warrants is not exempt from registration or qualification under applicable state blue sky laws or if we are unable to effect such registration or qualification. We will use our best efforts to register or qualify such shares under the blue sky laws of the state of residence in those states in which the Warrants were offered by us. Redemption of the outstanding Warrants could force an investor to (i) to exercise their Warrants and pay the exercise price therefor at a time when it may be disadvantageous for an investor to do so, (ii) for an investor to sell their Warrants at the then-current market price when they might otherwise wish to hold their Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of an investors Warrants.

In addition, we may redeem an investor's Warrants at any time after they become exercisable and prior to their expiration at a price of \$0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their Warrants prior to redemption for a number of Common Shares determined based on the redemption date and the fair market value of our Common Shares. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants, including because the number of shares received is capped at 0.361 Common Shares per warrant (subject to adjustment) irrespective of the remaining life of the Warrants. None of the Private Placement Warrants will be redeemable by us so long as they are held by the MAAC Sponsor or its permitted transferees.

***Our management will have the ability to require holders of our Warrants to exercise such Warrants on a cashless basis, which will cause holders to receive fewer Common Shares upon their exercise of the Warrants than they would have received had they been able to exercise their Warrants for cash.***

If we call the Public Warrants for redemption after the redemption criteria have been satisfied, our management will have the option to require any holder that wishes to exercise their warrant (including any Warrants held by the MAAC Sponsor, MAAC's former officers or directors, other purchasers of MAAC's founders' units, or their permitted transferees) to do so on a "cashless basis." If our management chooses to require holders to exercise their Warrants on a cashless basis, the number of Common Shares received by a holder upon exercise will be fewer than it would have been had such holder exercised his warrant for cash. This will have the effect of reducing the potential "upside" of the holder's investment in our company.

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

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

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

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

- a classified board of directors with staggered three-year terms;

- the ability of our board of directors to determine the powers, preferences and rights of preference shares and to cause us to issue the preference shares without shareholder approval;
- the ability of our board of directors to prevent the transfer of capital stock, or the exercise of rights with respect to our capital stock, if the effect of such transfer or exercise of rights would result in a shareholder holding more than 9.9% of the total issued and outstanding shares of our capital stock on a fully diluted basis; and
- requiring advance notice for shareholder proposals and nominations and placing limitations on convening shareholder meetings.

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

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

Our founder and certain of our largest shareholders hold a significant percentage of our Common Shares. As a result, these holders have the ability to substantially influence us and exert significant control through this ownership position and, in the case of certain holders, service on our board of directors. For example, these holders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. These holders' interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as these holders continue to own a significant amount of our equity, they will continue to be able to strongly influence and effectively control our decisions.

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

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

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

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

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

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

***Our founder and certain of our largest shareholders own a substantial portion of our Common Shares. As a result, there may be limited liquidity for our Common Shares.***

Our founder and certain of our largest shareholders hold a significant percentage of our Common Shares. Certain of these shareholders remain subject to lock-up arrangements in respect of a portion of their Common Shares and as a result there may be limited liquidity in the trading market for our Common Shares during the period in which these lock-up agreements are in effect. In addition, even once the applicable lock-up periods expire, the liquidity for our Common Shares may remain limited given the substantial holdings of such shareholders, which could make the price of our Common Shares more volatile and may make it more difficult for investors to buy or sell large amounts of our Common Shares.

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

Our may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our Common Shares unless you sell your shares of for a price greater than that which you paid for them.

***We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for you to enforce judgments against us or our directors and executive officers.***

We are an exempted company limited by shares incorporated under the laws of Bermuda. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the U.S., against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

***Bermuda law differs from the laws in effect in the U.S. and may afford less protection to our shareholders.***

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended (the “Companies Act”), which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal or would result in the violation of the company’s memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company’s affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder will waive any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the U.S., particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the U.S.

***There are regulatory limitations on the ownership and transfer of our Common Shares.***

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our Common Shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes Nasdaq. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our Common Shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the Nasdaq or another appointed stock exchange.

***We may become subject to unanticipated tax liabilities and higher effective tax rates.***

We are incorporated under the laws of Bermuda. We are centrally managed and controlled in the U.K., and under current U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, and subject to U.K.’s controlled foreign company rules, except where an exemption applies. We may

be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate, including as a result of the denial of treaty benefits that we may claim. Any such additional tax liability could materially adversely affect our results of operations.

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

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

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

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



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

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

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

***The IRS may not agree that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes.***

Under current U.S. federal income tax law, a corporation generally will be considered to be a U.S. corporation for U.S. federal income tax purposes only if it is created or organized in the United States or under the law of the United States or of any state thereof. Accordingly, under generally applicable U.S. federal income tax rules, since we were not created or organized in the United States or under the law of the United States or of any state thereof but are instead a Bermuda incorporated entity and tax resident of the U.K., we would generally be classified as a non-U.S. corporation. Section 7874 of the Internal Revenue Code of 1986, as amended (the “Code”) and the Treasury regulations promulgated thereunder, however, contain specific rules that may cause a non-U.S. corporation to be treated as a U.S. corporation for U.S. federal income tax purposes. If it were determined that we are treated as a U.S. corporation for U.S. federal income tax purposes under Section 7874 of the Code and the Treasury regulations promulgated thereunder, we would be liable for U.S. federal income tax on our income just like any other U.S. corporation and certain distributions made by us to our shareholders that are not “United States persons as defined in the Code (“U.S. holders”) would be subject to U.S. withholding tax. We believe that we should not be treated as a U.S. corporation for U.S. federal income tax purposes under Section 7874 of the Code. However, the application of Section 7874 of the Code is complex and is subject to detailed Treasury regulations that could be impacted by changes in such Treasury regulations with possible retroactive effect, and the interpretation of Treasury regulations relating to the required ownership of us is subject to uncertainty for which there is limited guidance regarding their application. Accordingly, there can be no assurance that the IRS will not take a contrary position to those described above or that a court will not agree with a contrary position of the IRS in the event of litigation. You are urged to consult your tax advisor to determine the tax consequences if the classification of us as a non-U.S. corporation is not respected.

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

A non-U.S. corporation is considered a CFC if more than 50% of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is

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

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

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

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

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

Treasury regulations adopted in 2021, or the (the “2021 Regulations”), modify certain of the rules described above. The 2021 Regulations generally apply to taxable years of shareholders beginning on or after January 14, 2021. A shareholder, however, may choose to apply such rules for any open taxable year beginning before January 14, 2021, provided that, with respect to a non-U.S. corporation being tested for PFIC status, the shareholder consistently applies certain of the provisions of the 2021 Regulations and certain other Treasury regulations for such year and all subsequent years. Investors who are U.S. holders should consult their own tax advisors regarding the impact and applicability of the 2021 Regulations.

Based on the foregoing, with respect to the taxable year that ended on March 31, 2022, we believe that we were not a PFIC based in part on our belief that we were not classified as a CFC in the taxable year that ended on March 31, 2022 and based upon the fair market value of our assets, including any goodwill and intangible property, and the nature and composition of our income and assets.

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

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

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

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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, United Kingdom SW1Y 4LB. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. Certain of our subsidiaries and affiliates also have business operations in New York, New York, Boston, Massachusetts and Basel, Switzerland.

Our subsidiary Roivant Sciences, Inc. subleases 83,340 square feet of office space located in New York, New York, pursuant to a sublease agreement that expires in October 2032. Certain of our subsidiaries and affiliates also lease office space in Boston, Massachusetts and Basel, Switzerland. We do not own any properties.

We believe that our and 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 began trading on The Nasdaq Global Market ("Nasdaq") under the symbol "ROIV" on October 1, 2021. Prior to that date, there was no public trading market for our Common Shares.

Warrants to purchase our Common Shares originally began trading on The Nasdaq Stock Market LLC as units under the symbol "MAACU" on October 6, 2020, in connection with the initial public offering of Montes Archimedes Acquisition Corp. ("MAAC"). Following the completion of the Business Combination with MAAC on September 30, 2021, we assumed MAAC's obligations under the warrants and they began trading on The Nasdaq Global Market under the symbol "ROIVW" on October 1, 2021.

#### Holders

As of June 21, 2022, there were 145 holders of record of our Common Shares and two holders of record of warrants to purchase our Common Shares. The actual number of holders of our Common Shares and warrants is greater than these numbers of record holders and includes stockholders who are beneficial owners but whose Common Shares or warrants 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.

#### Sales of Unregistered Securities and Use of Proceeds

On February 15, 2022, we issued 145,986 Common Shares to CF Principal Investments, LLC in consideration for its irrevocable commitment to purchase Common Shares pursuant to a Common Shares Purchase Agreement, dated as of February 14, 2022, by and between us and CF Principal Investments, LLC in connection with an equity line facility with an aggregate line of \$250.0 million.

On April 21, 2022, we issued 1,455,719 Common Shares to Silicon Therapeutics LLC in connection with the Agreement and Plan of Merger, dated as of February 2, 2021, by and among Roivant, Silicon Insite, Inc., Silicon TX China and Silicon Therapeutics LLC, as consideration in connection with the transaction, with an aggregate value of approximately \$5.4 million.

We issued the foregoing securities in transactions not involving an underwriter and not requiring registration under Section 5 of the Securities Act of 1933, as amended, in reliance on the exemption afforded by Section 4(a)(2) thereof.

Except as set forth above or reported in our Quarterly Reports on Form 10-Q for the quarters ended September 30, 2021 and December 31, 2021, there were no other sales of unregistered securities for the year ended March 31, 2022.

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**

We are building the next-generation "big pharma" company, organized to harness modern technologies and computational tools as well as the entrepreneurial spirit of nimble biotechnology companies at scale. Our mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity.

We are a diverse team of experienced drug developers, scientists, physicians, company builders, data scientists and engineers, biopharma investors, physicists and business development professionals dedicated to improving the lives of patients. At Roivant, we combine our team's extensive experience and multi-disciplinary expertise with innovative technologies to identify and advance potentially transformative medicines.

We deploy a hypothesis-driven approach to identify novel or clinically-validated targets and biological pathways in areas of high unmet medical need. We then seek to acquire, in-license or discover promising drug candidates against those targets or pathways. Our small molecule discovery engine is powered by leading computational physics and machine learning ("ML") capabilities for in silico drug design.

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

Our agile Vant model has allowed us to rapidly add capabilities in diverse therapeutic areas, including immunology, dermatology and oncology, and modalities, including biologics, topicals and bifunctional small molecules. The Vant model also enables a modular approach to the monetization of therapies we advance through development, allowing us to pursue commercialization of some products independently, while selectively establishing partnerships for other Vants or divesting of the Vants entirely.

Since our inception in 2014, we have focused substantially all of our efforts and financial resources on acquiring and developing our product candidates and expanding our platform and technologies. For the years ended March 31, 2022 and 2021, we incurred net losses of \$924.1 million and \$900.2 million, respectively. As of March 31, 2022, we had cash and cash equivalents of approximately \$2.1 billion and an accumulated deficit of approximately \$2.8 billion. Through March 31, 2022, we had not generated any revenue from the sale of our product candidates. Through our subsidiary Dermavant Sciences Ltd., we have launched our first commercial product, VTAMA<sup>®</sup> (tapinarof) cream, following approval by the FDA in May 2022. Through March 31, 2022, our revenue, primarily generated through license agreements as well as from subscription and service-based fees, has not been significant. Our operations to date have been financed primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements.

## **Recent Developments**

### ***Dermavant***

In May 2022, VTAMA cream was approved by the FDA as the first and only FDA-approved steroid-free topical medication in its class for the treatment of plaque psoriasis in adult patients.

Following the approval of VTAMA cream by the FDA in May 2022, Dermavant Sciences Ltd. (together with its wholly owned subsidiaries, “Dermavant”) received \$160.0 million in June 2022 pursuant to the terms of the revenue interest purchase and sale agreement (the “RIPSA”) as described in Note 7, “Long-Term Debt and Loan Commitment” of our audited financial statements.

Also, as a result of FDA approval, Dermavant achieved a regulatory milestone to GSK of £100.0 million (approximately \$126 million on the date of achievement), which will be paid within 70 calendar days of FDA approval. Additionally, the first sale of VTAMA cream in May 2022 resulted in the achievement of a milestone to Welicem Biotech Inc. of CAD\$25.0 million (approximately \$20 million on the date of achievement), which will be paid within 60 calendar days of the invoice date. Dermavant intends to primarily use the RIPSA proceeds for the payment of these obligations.

### ***Roivant***

We have implemented a company-wide cost optimization and pipeline reprioritization initiative to reduce our expected operating expenses and preserve our capital resources. As part of this initiative, we have discontinued the development of several programs, including ARU-1801, LSVT-1701, DMVT-502, DMVT-503, DMVT-504 and CVT-TCR-01, to focus our capital on the potentially most valuable and meaningful opportunities for patients in our pipeline, including our programs at newly launched Priovant. We elected to wind down the development of ARU-1801 after considering the future development costs of the program, the current market environment, and the clinical and commercial profile of the product candidate.

### ***Impact of COVID-19***

The COVID-19 pandemic continues to present global public health and economic challenges. Although some of our clinical development timelines have been impacted by delays related to the COVID-19 pandemic, we have not experienced material financial impact on our business and operations as a result of the COVID-19 pandemic. However, the impact on our future results will largely depend on future developments related to COVID-19, which are highly uncertain and cannot be predicted with confidence, such as the emergence of new variants, the ultimate duration and spread of the outbreak, the continuing impact of the COVID-19 pandemic on financial markets and the global economy, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain, treat, and prevent the disease, including the availability and effectiveness of vaccines.

For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors” included elsewhere in this Annual Report on Form 10-K.

## **Components of Results of Operations**

### ***Revenue, net***

Through March 31, 2022, we have not generated any revenues from the sale of our product candidates. Our revenue through March 31, 2022 primarily includes the recognition of upfront payments received in connection with license agreements. Revenue is also generated by subscription and service-based fees. Our revenue recognized from inception through March 31, 2022 has not been significant.

With the approval of VTAMA cream for the treatment of plaque psoriasis in adult patients by the FDA in May 2022, we began to recognize product revenues after our initial product launch.

### ***Cost of revenues***

Through March 31, 2022, 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. Our cost of revenues through March 31, 2022 has not been significant.

With the approval of VTAMA cream for the treatment of plaque psoriasis in adult patients by the FDA in May 2022, we began to recognize cost of product revenues after our initial product launch.

### ***Research and development expenses***

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

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

Research and development activities will continue to be central to our business model. We anticipate that our research and development expenses will increase for the foreseeable future as we advance our product candidates through preclinical studies and clinical trials, as well as acquire new product candidates. In addition, we expect our research and development expenses to increase in the future, including as a result of our small molecule discovery engine (“Roivant Discovery”), comprising advanced computational physics and machine learning capabilities, integrated with an in-house wet lab facility. Research and development expenses will also be driven by the number of drug candidates from Roivant Discovery that we advance through preclinical studies and clinical trials. We expect higher employee-related expenses, including higher share-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity.

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

- the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of our product candidates, and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;
- the number of doses that patients receive;
- the countries in which the trials are conducted;
- our ability to secure and leverage adequate CRO support for the conduct of clinical trials;
- our ability to establish an appropriate safety and efficacy profile for our product candidates;



- the timing, receipt and terms of any approvals from applicable regulatory authorities;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the significant and changing government regulation and regulatory guidance;
- our ability to establish clinical and commercial manufacturing capabilities, or make arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations due to the COVID-19 pandemic; and
- our ability to maintain a continued acceptable safety profile of our product candidates following approval of our product candidates.

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

#### ***Acquired in-process research and development expenses***

For the year ended March 31, 2022, we began reporting acquired in-process research and development (“IPR&D”) expense as a separate line item in our consolidated statements of operations. Acquired IPR&D expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. These expenses were previously recorded in “Research and development” on the consolidated statements of operations. Prior periods have been revised to conform to the current period presentation.

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

#### ***General and administrative expenses***

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, and benefits, for general and administrative personnel, including those responsible for the identification and acquisition or in-license of new drug candidates as well as for overseeing Vant operations and facilitating the use of our platform and technologies at Vants. General and administrative expenses also consist of legal and accounting fees, consulting services and other operating costs relating to corporate matters and daily operations. Additionally, general and administrative expenses include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates along with costs incurred relating to the integration of new technologies.

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

#### ***Change in fair value of investments***

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

well as our equity investment in Heracles Parent, L.L.C., the parent entity of the Datavant business (“Datavant”), following Datavant’s merger with a wholly-owned subsidiary of Heracles Parent, L.L.C., the parent company of CIOX Health, (the “Datavant Merger”) in July 2021 at which point our minority equity interest in Datavant became subject to the equity method of accounting. We have elected the fair value option to account for these investments.

#### ***Gain on sale of investment***

Gain on sale of investment resulted from the Datavant Merger in July 2021. Prior to the Datavant Merger, our investment in Datavant was accounted for using the measurement alternative to fair value. At closing of the Datavant Merger, we received approximately \$320 million in cash and a minority equity interest in the combined company, which became subject to the equity method of accounting. We recognized a gain as a result of this transaction.

#### ***Change in fair value of debt and liability instruments***

Change in fair value of debt and liability instruments primarily includes the unrealized (gain) loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including debt issued by a wholly-owned subsidiary of Dermavant Sciences Ltd. to NovaQuest Co-Investment Fund VIII, L.P. (the “NovaQuest Facility”), and other liability instruments, including warrant and earn-out share liabilities issued in connection with our business combination with Montes Archimedes Acquisition Corp. (“MAAC”) as well as options granted to Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) to purchase our ownership interests in certain subsidiaries (the “Sumitomo Options”) before the termination of those options in June 2021.

#### ***Gain on termination of Sumitomo Options***

Gain on termination of Sumitomo Options resulted from the completion of transactions contemplated by an Asset Purchase Agreement entered into with Sumitomo and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (“SPC”) in May 2021. The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire our ownership interest in certain subsidiaries; (ii) we transferred and assigned to SPC all of our intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively “Greater China”), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) Sumitomo agreed to pay us \$5.0 million in cash; and (iv) Sumitomo entered into an agreement with us to pursue future collaborations with Genevant Sciences Ltd. (“Genevant”). We received the cash payment, net of certain withholding taxes, in August 2021.

#### ***Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity***

Gain on deconsolidation of subsidiary resulted from the determination that we no longer had a controlling financial interest in certain subsidiaries. Gain on consolidation of unconsolidated entity resulted from the remeasurement of our previously held interest in Genevant following the consolidation of Genevant as of July 2020.

#### ***Other expense, net***

Other expense, net consists of interest expense resulting from interest accrued on long-term debt and the amortization of debt discount and issuance costs, losses from our equity method investment prior to consolidation in July 2020, interest income on our cash and cash equivalents, and other miscellaneous (income) expense.

## Income tax expense

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

## Net loss attributable to noncontrolling interests

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

## Results of Operations

### Comparison of the years ended March 31, 2022 and 2021

The following table sets forth our results of operations for the years ended March 31, 2022 and 2021:

	Years Ended March 31,		Change
	2022	2021	
	<i>(in thousands)</i>		
Revenue, net	\$ 55,286	\$ 23,795	\$ 31,491
Operating expenses:			
Cost of revenues	8,966	2,057	6,909
Research and development	483,035	236,626	246,409
Acquired in-process research and development	139,894	596,132	(456,238)
General and administrative	775,033	259,878	515,155
Total operating expenses	1,406,928	1,094,693	312,235
Loss from operations	(1,351,642)	(1,070,898)	(280,744)
Change in fair value of investments	87,291	(95,533)	182,824
Gain on sale of investment	(443,754)	—	(443,754)
Change in fair value of debt and liability instruments	(3,354)	29,845	(33,199)
Gain on termination of Sumitomo Options	(66,472)	—	(66,472)
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(5,041)	(115,364)	110,323
Other expense, net	3,435	8,701	(5,266)
Loss before income taxes	(923,747)	(898,547)	(25,200)
Income tax expense	369	1,686	(1,317)
Net loss	(924,116)	(900,233)	(23,883)
Net loss attributable to noncontrolling interests	(78,854)	(90,999)	12,145
Net loss attributable to Roivant Sciences Ltd.	<u>\$ (845,262)</u>	<u>\$ (809,234)</u>	<u>\$ (36,028)</u>

*Variance analysis for years ended March 31, 2022 and 2021*

*Revenue, net*

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	
	<i>(in thousands)</i>		
Revenue, net	\$ 55,286	\$ 23,795	\$31,491

Revenue, net increased by \$31.5 million to \$55.3 million for the year ended March 31, 2022 compared to \$23.8 million for the year ended March 31, 2021. The increase was primarily related to payments received in connection with license agreements and the license of technology. Additionally, we recognized revenue relating to the sales of clinical product as well as milestone income at Dermavant. Revenue generated was not significant in either period presented.

*Cost of revenues*

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	
	<i>(in thousands)</i>		
Cost of revenues	\$ 8,966	\$ 2,057	\$6,909

Cost of revenues increased by \$6.9 million to \$9.0 million for the year ended March 31, 2022 compared to \$2.1 million for the year ended March 31, 2021, consistent with increased revenue. Cost of revenues was not significant in either period presented.

*Research and development expenses*

For the years ended March 31, 2022 and 2021, our research and development expenses consisted of the following:

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	
	<i>(in thousands)</i>		
<i>Program-specific costs:</i>			
Batoclimab	\$ 67,181	\$ 49,236	\$ 17,945
Tapinarof	64,496	34,002	30,494
Brepocitinib	24,890	—	24,890
ARU-1801	23,312	24,347	(1,035)
AFVT-2101	12,657	3,782	8,875
ARU-2801	12,031	784	11,247
LSVT-1701	11,067	3,383	7,684
Namilumab	8,745	820	7,925
Other program-specific costs	60,660	45,558	15,102
Total program-specific costs	<u>285,039</u>	<u>161,912</u>	<u>123,127</u>
<i>Unallocated internal costs:</i>			
Share-based compensation	63,735	22,637	41,098
Personnel-related expenses	103,827	45,646	58,181
Other expenses	30,434	6,431	24,003
<b>Total research and development expenses</b>	<u>\$483,035</u>	<u>\$236,626</u>	<u>\$246,409</u>

Research and development expenses increased by \$246.4 million to \$483.0 million for the year ended March 31, 2022 compared to \$236.6 million for the year ended March 31, 2021, primarily due to increases in program-specific costs of \$123.1 million, personnel-related expenses of \$58.2 million, and share-based compensation of \$41.1 million.

The increase of \$123.1 million in program-specific costs largely reflects the progression of our programs and drug discovery. Program-specific costs for Dermavant's tapinarof program increased by \$30.5 million, largely resulting from purchases of clinical product as we prepared for commercial launch and incurred costs associated with our Phase 3 clinical program in atopic dermatitis. Program specific costs for Priovant Therapeutics, Inc.'s ("Priovant") brepocitinib program were \$24.9 million for the year ended March 31, 2022, reflecting costs incurred since the acquisition of brepocitinib in September 2021. Program-specific costs for Immunovant's batoclimab program increased by \$17.9 million, primarily reflecting activities to advance the clinical development of batoclimab in current and potentially new indications.

The increase of \$58.2 million in personnel-related expenses was primarily driven by an increase in headcount to support the progression of our programs and drug discovery.

The increase of \$41.1 million in share-based compensation expense was primarily due to the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination in September 2021, resulting in the recognition of a one-time catch-up expense of \$22.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination and continued recognition of expense over the requisite service periods. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met.

#### *Acquired in-process research and development expenses*

	<u>Years Ended March 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>Change</u>
	<i>(in thousands)</i>		
Consideration for the purchase of IPR&D	\$ 97,412	\$ 591,916	\$ (494,504)
Development milestone payments	42,482	4,216	38,266
<b>Total acquired in-process research and development expenses</b>	<b><u>\$ 139,894</u></b>	<b><u>\$ 596,132</u></b>	<b><u>\$ (456,238)</u></b>

Acquired in-process research and development expenses decreased by \$456.2 million to \$139.9 million for the year ended March 31, 2022 compared to \$596.1 million for the year ended March 31, 2021. The decrease was primarily due to higher consideration for the purchase of IPR&D during the year ended March 31, 2021 as a result of the following: consideration of \$399.6 million attributed to IPR&D relating to the acquisition of the business of Silicon Therapeutics; consideration of \$116.5 million relating to the stock purchase agreement to acquire Oncopia; \$41.4 million attributed to IPR&D as part of the consolidation of Genevant, which was previously accounted for as an equity method investment; and consideration relating to the licensing and strategic collaboration agreement with Affimed N.V. During the year ended March 31, 2022, acquired in-process research and development expenses included consideration for the purchase of IPR&D of \$82.1 million relating to the acquisition of brepocitinib by Priovant and \$14.1 million relating to a license agreement entered by Hemavant Sciences GmbH with Eisai Co., Ltd. Additionally, acquired in-process research and development expenses for year ended March 31, 2022 included a one-time milestone expense of CAD\$50.0 million (\$39.3 million) due to the achievement of a development milestone relating to Dermavant's tapinarof program.

## General and administrative expenses

	Years Ended March 31,		Change
	2022	2021	
General and administrative	\$775,033	<i>(in thousands)</i> \$259,878	\$515,155

General and administrative expenses increased by \$515.2 million to \$775.0 million for the year ended March 31, 2022 compared to \$259.9 million for the year ended March 31, 2021. The increase was primarily due to increases in share-based compensation expense of \$438.9 million primarily as a result of the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination in September 2021, resulting in the recognition of a one-time catch-up expense of \$350.0 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination and continued recognition of expense over the requisite service periods. Historically, we did not recognize share-based compensation expense related to these equity instruments as the liquidity event requirement had not been met and was not deemed probable of being met. Additionally, general and administrative expenses for Dermavant have increased as we prepared for commercial launch.

## Change in fair value of investments

	Years Ended March 31,		Change
	2022	2021	
Change in fair value of investments	\$87,291	<i>(in thousands)</i> \$(95,533)	\$182,824

Change in fair value of investments was an unrealized loss of \$87.3 million and unrealized gain of \$95.5 million for the years ended March 31, 2022 and 2021, respectively. The change of \$182.8 million was primarily driven by changes in the public share prices of Arbutus and Sio as well as the change in fair value of our investment in Datavant following the completion of the Datavant Merger in July 2021.

## Gain on sale of investment

	Years Ended March 31,		Change
	2022	2021	
Gain on sale of investment	\$(443,754)	<i>(in thousands)</i> \$—	\$(443,754)

Gain on sale of investment was \$443.8 million for the year ended March 31, 2022 due to the Datavant Merger in July 2021 at which point we received approximately \$320 million in cash and a minority equity stake in the combined company. See “Components of Results of Operations—Gain on sale of investment” above for additional information.

## Change in fair value of debt and liability instruments

	Years Ended March 31,		Change
	2022	2021	
Change in fair value of debt and liability instruments	\$(3,354)	<i>(in thousands)</i> \$29,845	\$(33,199)

Change in fair value of debt and liability instruments was an unrealized gain of \$3.4 million and unrealized loss of \$29.8 million for the years ended March 31, 2022 and 2021, respectively. Change in fair value of debt and liability instruments for the year ended March 31, 2022 primarily consisted of an unrealized gain of \$30.8 million

relating to the warrant and earn-out share liabilities issued as part of the Business Combination, partially offset by an unrealized loss of \$27.3 million relating to the NovaQuest facility, which was largely due to the passage of time and increased probabilities of success as a result of advancement in the stage of development of the product candidate. Change in fair value of debt and liability instruments for the year ended March 31, 2021 primarily consisted of an unrealized loss of \$61.0 million relating to the NovaQuest Facility, partially offset by an unrealized gain of \$33.5 million relating to the Sumitomo Options.

#### ***Gain on termination of Sumitomo Options***

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	
	<i>(in thousands)</i>		
Gain on termination of Sumitomo Options	\$(66,472)	\$ —	\$(66,472)

Gain on termination of Sumitomo Options was \$66.5 million for the year ended March 31, 2022 due to the completion of transactions contemplated by the Asset Purchase Agreement entered into with Sumitomo and SPC. See “Components of Results of Operations—Gain on termination of Sumitomo Options” above for additional information.

#### ***Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity***

	<u>Years Ended March 31,</u>		<u>Change</u>
	<u>2022</u>	<u>2021</u>	
	<i>(in thousands)</i>		
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	\$(5,041)	\$(115,364)	\$ 110,323

Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity was \$5.0 million and \$115.4 million for the years ended March 31, 2022 and 2021, respectively. The gain of \$5.0 million for the year ended March 31, 2021 resulted from the deconsolidation of a subsidiary. Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity for the year ended March 31, 2021 primarily related to a gain of \$86.5 million on the deconsolidation of Datavant in April 2020 and a gain of \$28.8 million resulting from the remeasurement of our previously held interest in Genevant upon its consolidation in July 2020.

#### **Liquidity and Capital Resources**

For the years ended March 31, 2022 and 2021, we incurred net losses of \$924.1 million and \$900.2 million, respectively. As of March 31, 2022, we had cash and cash equivalents of approximately \$2.1 billion and our accumulated deficit was approximately \$2.8 billion. Through March 31, 2022, we have not generated any revenues from the sale of our product candidates. Through our subsidiary Dermavant, we have launched our first commercial product, VTAMA cream, following approval by the FDA in May 2022. Our revenue through March 31, 2022, primarily generated through license agreements as well as from subscription and service-based fees, has not been significant.

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

- Contractual payments related to our long-term debt (see Note 7, “Long-Term Debt and Loan Commitment” of our audited financial statements);
- obligations under our operating leases (see Note 12, “Leases” of our audited financial statements);
- certain commitments to Palantir Technologies Inc. (“Palantir”) totaling \$30.0 million related to a master subscription agreement entered in May 2021 for access to Palantir’s proprietary software for a five-year period; and

- certain commitments to Samsung Biologics Co., Ltd. (“Samsung”) pursuant to a Product Service Agreement entered between Immunovant and Samsung by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. The minimum purchase commitment related to this agreement is estimated to be approximately \$36.0 million.

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

In May 2022, VTAMA (tapinarof) cream was approved by the FDA as the first and only FDA-approved steroid-free topical medication in its class for the treatment of plaque psoriasis in adult patients. As a result of FDA approval, Dermavant achieved a regulatory milestone to GSK of £100.0 million (approximately \$126 million on the date of achievement), which will be paid within 70 calendar days of FDA approval. Additionally, the first sale of VTAMA cream in May 2022 resulted in the achievement of a milestone to Welichem Biotech Inc. of CAD\$25.0 million (approximately \$20 million on the date of achievement), which will be paid within 60 calendar days of the invoice date. Dermavant intends to primarily use the RPSA proceeds for the payment of these obligations.

Apart from the above mentioned regulatory milestones related to VTAMA (tapinarof) cream, the payment obligations under our asset acquisition and license agreements are contingent upon future events and the amount, timing, and likelihood of such payments are not know.

We enter into agreements in the normal course of business with CROs and other vendors for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

We expect our existing cash and cash equivalents will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next twelve months based on current operating plans and financial forecasts. However, we have based this estimate on assumptions that may prove to be wrong, which may require us to use our capital resources sooner than expected. See “Forward-Looking Statements” and “Risk Factors” in this Annual Report on Form 10-K.

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.

#### RSL Equity Financing Transactions

Since inception, we have completed multiple equity financing transactions, including the following:

In December 2019, in connection with the Sumitomo Transaction, we raised net proceeds of approximately \$999.2 million in connection with the sale of our common shares to Sumitomo.

In September 2021, we completed our Business Combination with MAAC, a special purpose acquisition company, as well as concurrent PIPE Financing. In connection with the Business Combination and PIPE Financing, we received approximately \$213.4 million in cash at closing.

On February 14, 2022, we entered into a committed equity facility (the “Facility”) with an affiliate of Cantor Fitzgerald & Co. (“Cantor”). Under the terms of the Facility, Cantor has committed to purchase up to an aggregate of \$250.0 million in our common shares from time to time at our request, subject to certain limitations and the satisfaction of certain conditions. Any sales of our common shares to Cantor under the Facility will be made at 99% of the volume-weighted average price of our common shares on Nasdaq on a given trading day. In



consideration for entry into the Facility, we paid Cantor an upfront commitment fee in the form of 145,986 common shares. As of March 31, 2022, \$250.0 million of our common shares remained available for sale under the Facility.

#### Sumitomo Transaction

In December 2019, we closed the Sumitomo Transaction, including the transfer of our ownership interest in five Vants—Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd.—to Sumitovant Biopharma Ltd. (“Sumitovant”), a wholly-owned subsidiary of Sumitomo. In addition, in connection with the Sumitomo Transaction, we (i) granted Sumitomo options to purchase all, or in the case of Dermavant, 75%, of our ownership interests in six other subsidiaries and (ii) provided Sumitomo and Sumitovant with certain rights over and access to our proprietary technology platforms, DrugOme and Digital Innovation. In exchange for these components of the Sumitomo Transaction, we received approximately \$1.9 billion in cash, which was in addition to the approximately \$999.2 million from the sale of our common shares to Sumitomo as discussed above.

In June 2021, we completed a transaction with Sumitomo pursuant to which Sumitomo terminated its existing options to acquire our equity interests in certain of our subsidiaries. See “Components of Results of Operations—Gain on termination of Sumitomo Options” above for additional information.

#### Consolidated Vant Equity Financing Transactions

Since inception, we have completed multiple Vant equity financing transactions, including the following:

##### *Immunovant*

In December 2019, Immunovant raised \$111.0 million (including \$5.1 million related to common shares purchased by us) through a business combination with Health Sciences Acquisition Corporation, a special purpose acquisition company.

Additionally, during the years ended March 31, 2021 and 2020, Immunovant issued shares of common stock for an aggregate net proceeds of \$384.9 million (including an aggregate of \$27.5 million of shares of common stock purchased by us) in private financings, underwritten public offerings, and warrant exercises.

##### *Proteovant*

In December 2020, following Proteovant Sciences, Inc.’s (“Proteovant”) acquisition of Oncopia in November 2020, SK, Inc. (formerly known as SK Holdings Co., Ltd.) (“SK”) entered into a subscription agreement (the “Subscription Agreement”) pursuant to which SK agreed to make a \$200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date. In January 2021, in accordance with the terms of the Subscription Agreement, SK made the first payment of \$100.0 million to Proteovant. In July 2021, Proteovant collected the subscription receivable relating to the second \$100.0 million payment due under the SK Subscription Agreement.

#### Consolidated Vant Debt Financings

Since inception, we have completed multiple Vant debt financings, including the following:

##### *Dermavant*

In May 2019, Dermavant entered into a loan and security agreement (the “Hercules Loan Agreement”) with Hercules, pursuant to which Dermavant borrowed an aggregate of \$20.0 million. In May 2021, all amounts outstanding under the Hercules Loan Agreement were repaid using the proceeds from the \$40.0 million senior secured credit facility entered into by Dermavant in May 2021, and Dermavant terminated the Hercules Loan Agreement.

Following the approval of VTAMA cream by the FDA in May 2022, Dermavant received \$160.0 million in June 2022 pursuant to the terms of the revenue interest purchase and sale agreement entered with XYQ Luxco, NovaQuest Co-Investment Fund XVII, L.P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L.P., together with U.S. Bank National Association, as collateral agent. Under the terms of the RIPSAs, the Purchasers procured a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States, up to a cap of \$344.0 million, in exchange for \$160.0 million in committed funding to be paid to Dermavant, conditional based on the approval of tapinarof by the FDA. As described above, Dermavant intends to primarily use the RIPSAs proceeds for the payment of certain one-time milestone obligations that became payable upon the approval and commercialization of VTAMA (tapinarof) cream for the treatment of plaque psoriasis in adult patients in the United States.

### Other

#### *Datavant*

In July 2021, we received approximately \$320 million in cash as a result of the Datavant Merger.

#### ***Funding Requirements***

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

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

We expect to continue to finance our cash needs through a combination of our cash on hand and future equity offerings, debt financings, sales of subsidiaries, and collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of

these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

### **Cash Flows**

The following table sets forth a summary of our cash flows for the years ended March 31, 2022 and 2021:

	<b>Years Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
	<i>(in thousands)</i>	
Net cash used in operating activities	\$(677,729)	\$(552,138)
Net cash provided by (used in) investing activities	\$ 303,295	\$ (31,702)
Net cash provided by financing activities	\$ 306,792	\$ 456,264

### **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, 2022, cash used in operating activities increased by \$125.6 million to \$677.7 million compared to the year ended March 31, 2021. This increase was primarily driven by an increase in cash required to fund operations, particularly as a result of the progression of Vant programs and payments made for a one-time milestone expense and purchases of clinical product as we prepared for a commercial launch of VTAMA cream and incurred costs associated with our Phase 3 clinical program in atopic dermatitis at Dermavant. Additionally, in November 2021, we made a \$50.0 million cash payment related to the previously-disclosed \$100.0 million second tranche of consideration due in connection with the acquisition of Silicon Therapeutics, LLC. The remaining consideration was settled by the issuance of 6,348,057 of our common shares.

### **Investing Activities**

Cash flow from investing activities includes cash used for acquisitions, net of cash acquired; proceeds from investments; dispositions, net of cash disposed; capital expenditures; and purchases of equity securities and other investments.

For the year ended March 31, 2022, cash flow from investing activities changed by \$335.0 million to net cash provided by investing activities of \$303.3 million from net cash used in investing activities of \$31.7 million for the year ended March 31, 2021. This change in cash flow from investing activities is primarily due to approximately \$320 million in cash we received as a result of the Datavant Merger.

## ***Financing Activities***

For the year ended March 31, 2022, cash provided by financing activities decreased by \$149.5 million to \$306.8 million compared to the year ended March 31, 2021. During the year ended March 31, 2022, proceeds were generated by the completion of our Business Combination and PIPE financing in September 2021, payment of the subscription receivable due to Proteovant by SK in July 2021, and the senior secured credit facility entered into by Dermavant and certain of its subsidiaries with XYQ Luxco, as lender, and U.S. Bank National Association, as collateral agent, partially offset by cash used to repay all amounts outstanding under a previously existing loan and security agreement with Hercules Capital, Inc. During the year ended March 31, 2021, cash provided by financing activities was primarily driven by the issuance of equity by our majority-owned subsidiaries, Immunovant and Proteovant.

## **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, and 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.

## ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred.

We accrue expense for preclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine such estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion and the agreed-upon fee to be paid for such services. However, actual costs and timing of preclinical studies and clinical trials are highly uncertain, subject to risks, and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

## ***Share-Based Compensation***

We recognize compensation costs related to share-based awards granted to employees, directors, and consultants based on the estimated fair value of the awards on the date of grant. The grant date fair value of the stock-based awards is recognized over the requisite service period, which is generally the vesting period of the respective awards. We may grant awards with graded-vesting features. When such awards have only service vesting requirements, we elected to record share-based compensation expense on a straight-line basis. If awards with graded-vesting features contain performance or market conditions, then we record share-based compensation expense using the accelerated attribution method.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including the fair value of our common shares prior to our initial public offering, volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These subjective assumptions are estimated as follows:

*Fair value of common share*—Prior to the closing of the Business Combination, as a privately held company, we estimated the fair value of the shares of common stock underlying our share-based awards on each grant date. To determine the fair value of our common shares underlying option grants, we considered, among other things, valuations of our common share prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The estimation of the fair value of the common shares considered factors including the following:

- the prices of our common shares sold to investors in arm's length transactions;
- the estimated present value of our future cash flows;
- our business, financial condition and results of operations;
- our forecasted operating performance;
- the illiquid nature of our common shares;
- industry information such as market size and growth;
- market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and
- macroeconomic conditions.

We apply a similar methodology to estimate the fair value of the shares of common stock underlying share-based awards issued by our privately held Vants. Following the closing of the Company's business combination with MAAC, our common shares became publicly traded and we began determining the fair value of each common share underlying share-based awards based on the closing price of our common shares as reported by Nasdaq on the date of grant. Therefore, it will not be necessary to determine the fair value of the new stock-based award pursuant to the methodology described above.

*Expected term*—We have generally elected to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

*Expected volatility*—Prior to the closing of the Business Combination, we were a privately held company and did not have any trading history for our common shares; accordingly, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We apply similar methodology to estimate the expected volatility at our privately held Vants. Because we do not have an extended trading history for our shares of common stock since the closing of the Business Combination, the method used to estimate the expected volatility remained unchanged.

*Risk-free interest rate*—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options at the time of the grant.

*Expected dividend yield*—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options; therefore, we have estimated the dividend yield to be zero.

### **Recently Adopted Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, “Summary of Significant Accounting Policies” in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

### **Implications of Being an Emerging Growth Company and Smaller Reporting Company**

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including the requirement that our internal control over financial reporting be audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, certain requirements related to the disclosure of executive compensation in this Annual Report on Form 10-K and in our periodic reports and proxy statements, and the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments. We have also taken advantage of the ability to provide reduced disclosure of financial information in this Annual Report on Form 10-K, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. However, because we have taken advantage of certain reduced reporting requirements, the information contained herein may be different from the information you receive from other public companies in which you hold shares.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the first sale of Roivant common shares pursuant to an effective registration statement or (b) in which we have total annual gross revenue of at least \$1.07 billion (as adjusted for inflation pursuant to SEC rules from time to time), and (2) the date on which (x) we are deemed to be a large accelerated filer, which means the market value of Roivant common shares that are held by non-affiliates exceeds \$700 million as of the prior September 30th, or (y) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the prior three-year period.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common shares held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds \$700 million as of the end of that year’s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies more difficult.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Under SEC rules and regulations, because we are considered to be a “smaller reporting company,” we are not required to provide the information required by this item in this report.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Index to Consolidated Financial Statements**

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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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, shareholders' equity and redeemable noncontrolling interest and cash flows for each of the two years in the period ended March 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2022, in conformity with U.S. generally accepted accounting principles.

**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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Iselin, New Jersey  
June 28, 2022

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

	<u>March 31, 2022</u>	<u>March 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,060,400	\$ 2,055,044
Restricted cash	3,903	77,701
Other current assets	82,220	54,250
Total current assets	2,146,523	2,186,995
Property and equipment, net	25,905	14,749
Operating lease right-of-use assets	61,044	62,279
Restricted cash, net of current portion	9,731	8,931
Investments measured at fair value	325,834	188,978
Long-term investment	—	100,563
Other assets	16,092	27,197
Total assets	<u>\$ 2,585,129</u>	<u>\$ 2,589,692</u>
<b>Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 34,583	\$ 20,550
Accrued expenses	127,531	76,936
Operating lease liabilities	11,398	12,313
Deferred consideration liability	—	100,000
Deferred revenue	10,147	5,918
Other current liabilities	708	3,244
Total current liabilities	184,367	218,961
Liability instruments measured at fair value	44,912	67,893
Operating lease liabilities, noncurrent	62,468	62,384
Long-term debt (includes \$177,400 and \$150,100 accounted for under the fair value option at March 31, 2022 and 2021, respectively)	210,025	170,280
Deferred revenue, noncurrent	13,740	—
Other liabilities	8,183	8,169
Total liabilities	<u>523,695</u>	<u>527,687</u>
Commitments and contingencies (Note 13)		
Redeemable noncontrolling interest	22,491	22,491
Shareholders' equity: <sup>(1)</sup>		
Common shares, par value \$0.0000000341740141 per share, 7,000,000,000 shares authorized and 694,975,965 and 651,576,293 shares issued and outstanding at March 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	4,421,614	3,814,805
Subscription receivable	—	(100,000)
Accumulated deficit	(2,763,724)	(1,918,462)
Accumulated other comprehensive (loss) income	(946)	1,445
Shareholders' equity attributable to Roivant Sciences Ltd.	1,656,944	1,797,788
Noncontrolling interests	381,999	241,726
Total shareholders' equity	<u>2,038,943</u>	<u>2,039,514</u>
Total liabilities, redeemable noncontrolling interest and shareholders' equity	<u>\$ 2,585,129</u>	<u>\$ 2,589,692</u>

(1) Retroactively restated for the stock subdivision as described in Note 3.

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

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

	Years Ended March 31,	
	2022	2021
Revenue, net	\$ 55,286	\$ 23,795
Operating expenses:		
Cost of revenues	8,966	2,057
Research and development (includes \$63,735 and \$22,637 of share-based compensation expense for the years ended March 31, 2022 and 2021, respectively)	483,035	236,626
Acquired in-process research and development	139,894	596,132
General and administrative (includes \$501,221 and \$62,321 of share-based compensation expense for the years ended March 31, 2022 and 2021, respectively)	775,033	259,878
Total operating expenses	1,406,928	1,094,693
Loss from operations	(1,351,642)	(1,070,898)
Change in fair value of investments	87,291	(95,533)
Gain on sale of investment	(443,754)	—
Change in fair value of debt and liability instruments	(3,354)	29,845
Gain on termination of Sumitomo Options	(66,472)	—
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(5,041)	(115,364)
Other expense, net	3,435	8,701
Loss before income taxes	(923,747)	(898,547)
Income tax expense	369	1,686
Net loss	(924,116)	(900,233)
Net loss attributable to noncontrolling interests	(78,854)	(90,999)
Net loss attributable to Roivant Sciences Ltd.	\$ (845,262)	\$ (809,234)
Net loss per common share—basic and diluted <sup>(1)</sup>	\$ (1.26)	\$ (1.28)
Weighted average shares outstanding—basic and diluted <sup>(1)</sup>	669,753,458	630,046,720

<sup>(1)</sup> Retroactively restated for the stock subdivision as described in Note 3.

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

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

	<u>Years Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Net loss	\$ (924,116)	\$ (900,233)
Other comprehensive loss:		
Foreign currency translation adjustment	(2,271)	3,826
Total other comprehensive (loss) income	(2,271)	3,826
Comprehensive loss	(926,387)	(896,407)
Comprehensive loss attributable to noncontrolling interests	(78,734)	(90,967)
Comprehensive loss attributable to Roivant Sciences Ltd.	<u>\$ (847,653)</u>	<u>\$ (805,440)</u>

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

**ROIIVANT SCIENCES LTD.**  
**Consolidated Statements of Shareholders' Equity and Redeemable Noncontrolling Interest**  
*(in thousands, except share data)*

	Shareholders' Equity <sup>(1)</sup>									
	Redeemable Noncontrolling Interest	Common Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Noncontrolling Interests	Total Shareholders' Equity
		Shares	Amount			Income	(Loss)			
<b>Balance at March 31, 2020</b>	\$ 22,491	628,779,048	\$ —	\$3,143,739	\$ —	\$ (2,349)	\$ (1,109,228)	\$ 54,042	\$ 2,086,204	
Issuance of the Company's common shares	—	21,077,155	—	301,744	—	—	—	—	301,744	
Issuance of subsidiary common shares, net	—	—	—	324,995	(100,000)	—	—	231,102	456,097	
Issuance of subsidiary common shares to the Company	—	—	—	(11,692)	—	—	—	11,692	—	
Exercise of subsidiary stock options and vesting of subsidiary restricted stock units	—	—	—	522	—	—	—	385	907	
Deconsolidation of subsidiary	—	—	—	—	—	—	—	(3,054)	(3,054)	
Consolidation of unconsolidated entity	—	—	—	—	—	—	—	9,178	9,178	
Repurchase of equity awards	—	—	—	(113)	—	—	—	—	(113)	
Cash contribution to majority-owned subsidiaries	—	—	—	(1,642)	—	—	—	1,642	—	
Share-based compensation	—	1,720,090	—	57,252	—	—	—	27,706	84,958	
Foreign currency translation adjustment	—	—	—	—	—	3,794	—	32	3,826	
Net loss	—	—	—	—	—	—	(809,234)	(90,999)	(900,233)	
<b>Balance at March 31, 2021</b>	<u>\$ 22,491</u>	<u>651,576,293</u>	<u>\$ —</u>	<u>\$3,814,805</u>	<u>\$ (100,000)</u>	<u>\$ 1,445</u>	<u>\$ (1,918,462)</u>	<u>\$ 241,726</u>	<u>\$ 2,039,514</u>	
Issuance of subsidiary warrants	—	—	—	2,051	—	—	—	24	2,075	
Issuance of the Company's common shares upon closing of Business Combination and PIPE Financing, net of issuance costs	—	32,372,478	—	129,097	—	—	—	—	129,097	
Issuance of the Company's common shares related to settlement of transaction consideration	—	840,398	—	—	—	—	—	—	—	
Issuance of subsidiary preferred shares	—	—	—	—	—	—	—	70,000	70,000	
Issuance of subsidiary common and preferred shares to the Company	—	—	—	(52,189)	—	—	—	52,189	—	
Payment of subscription receivable	—	—	—	(40,000)	100,000	—	—	40,000	100,000	
Repurchase of equity awards	—	—	—	—	—	—	—	(2,247)	(2,247)	
Issuance of the Company's common shares	—	7,369,000	—	57,167	—	—	—	—	57,167	
Issuance of common stock upon warrants exercise	—	60,021	—	778	—	—	—	—	778	
Stock options exercised and restricted stock units vested and settled	—	2,757,775	—	412	—	—	—	—	412	
Deconsolidation of subsidiary	—	—	—	—	—	—	—	3,578	3,578	
Cash contributions to majority-owned subsidiaries	—	—	—	(10,219)	—	—	—	10,219	—	
Share-based compensation	—	—	—	519,712	—	—	—	45,244	564,956	
Foreign currency translation adjustment	—	—	—	—	—	(2,391)	—	120	(2,271)	
Net loss	—	—	—	—	—	—	(845,262)	(78,854)	(924,116)	
<b>Balance at March 31, 2022</b>	<u>\$ 22,491</u>	<u>694,975,965</u>	<u>\$ —</u>	<u>\$4,421,614</u>	<u>\$ —</u>	<u>\$ (946)</u>	<u>\$ (2,763,724)</u>	<u>\$ 381,999</u>	<u>\$ 2,038,943</u>	

(1) Retroactively restated for the stock subdivision as described in Note 3.

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

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

	<b>Years Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (924,116)	\$ (900,233)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash acquired in-process research and development	78,223	351,523
Share-based compensation	564,956	84,958
Change in fair value of investments	87,291	(95,533)
Gain on sale of investment	(443,754)	—
Change in fair value of debt and liability instruments	(3,354)	29,845
Gain on deconsolidation of subsidiary and consolidation of unconsolidated entity	(5,041)	(115,364)
Gain on termination of Sumitomo Options	(61,472)	—
Loss from equity method investment	—	3,750
Other	13,819	16,978
Changes in assets and liabilities, net of effects from acquisition and divestiture:		
Accounts payable	15,403	3,752
Accrued expenses	50,595	9,225
Deferred consideration liability	(50,000)	100,000
Operating lease liabilities	(6,865)	(5,497)
Deferred revenue	17,969	2,297
Other	(11,383)	(37,839)
Net cash used in operating activities	<u>(677,729)</u>	<u>(552,138)</u>
<b>Cash flows from investing activities:</b>		
Proceeds from sale of investment	320,170	—
Purchase of property and equipment	(17,436)	(5,806)
Other	561	(25,896)
Net cash provided by (used in) investing activities	<u>303,295</u>	<u>(31,702)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from Business Combination and PIPE Financing	213,424	—
Proceeds from issuance of subsidiary common shares, net of issuance costs paid	—	455,756
Proceeds from payment of subscription receivable	100,000	—
Proceeds from subsidiary debt financings, net of financing costs paid	36,400	—
Repayment of long-term debt by subsidiary	(21,590)	—
Payment of offering costs and loan origination costs	(20,297)	(286)
Other	(1,145)	794
Net cash provided by financing activities	<u>306,792</u>	<u>456,264</u>
Net change in cash, cash equivalents and restricted cash	<u>(67,642)</u>	<u>(127,576)</u>
Cash, cash equivalents and restricted cash at beginning of period	2,141,676	2,269,252
Cash, cash equivalents and restricted cash at end of period	<u>\$ 2,074,034</u>	<u>\$ 2,141,676</u>
<b>Non-cash investing and financing activities:</b>		
Subscription receivable related to issuance of subsidiary common shares	\$ —	\$ 100,000
Other	\$ 6,035	\$ 4,531
<b>Supplemental disclosure of cash paid:</b>		
Income taxes paid	\$ 916	\$ 4,076
Interest paid	\$ 5,535	\$ 2,017

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

## Notes to 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 health by rapidly delivering innovative medicines and technologies to patients. The Company does this by building biotech and healthcare technology companies (“Vants”) and deploying technology to drive greater efficiency in research and development and commercialization. In addition to biopharmaceutical subsidiaries, the Company also builds technology Vants focused on improving the process of developing and commercializing medicines. The Company was founded on April 7, 2014 as a Bermuda exempted limited company.

VTAMA® (tapinarof) cream was approved by the United States Food and Drug Administration (“FDA”) in May 2022 as the first and only FDA-approved steroid-free topical medication in its class for the treatment of plaque psoriasis in adult patients.

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

On September 30, 2021, RSL completed its business combination with Montes Archimedes Acquisition Corp. (“MAAC”), a special purpose acquisition company, and began trading on Nasdaq under the ticker symbol “ROIV.” Refer to Note 3, “Business Combination with MAAC” for additional details.

**(B) Liquidity**

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2022, the Company had cash and cash equivalents of approximately \$2.1 billion and its accumulated deficit was approximately \$2.8 billion. For the years ended March 31, 2022 and 2021, the Company incurred net losses of \$924.1 million and \$900.2 million, respectively. The Company has historically financed its operations primarily through the sale of equity securities, sale of subsidiary interests, debt financings and revenue generated from licensing and collaboration arrangements. Through March 31, 2022, the Company had not generated any revenue from the sale of its product candidates. Through its subsidiary Dermavant Sciences Ltd., the Company has launched its first commercial product, VTAMA cream, following approval by the FDA in May 2022.

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

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates or take other steps to conserve capital. The Company expects its existing cash and cash equivalents will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these consolidated financial statements.

## **Note 2—Summary of Significant Accounting Policies**

### **(A) Basis of Presentation and Principles of Consolidation**

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30, and December 31.

The accompanying 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. 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 percentage of common stock ownership interest retained in the respective operations by the noncontrolling parties. The Company presents noncontrolling interests as a component of shareholders' equity on its consolidated balance sheets.

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

### **(B) Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses, contingent liabilities, share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of March 31, 2022 and through the issuance of these consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

### **(C) Concentrations**

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



The Company has long-lived assets in different geographic locations. As of March 31, 2022 and 2021, a majority of the Company's long-lived assets were located in the United States.

**(D) Cash, Cash Equivalents, and Restricted Cash**

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

Restricted cash classified as a current asset consists of legally restricted non-interest bearing deposit accounts relating to the Company's corporate credit card programs. Restricted cash classified as a long-term asset consists of restricted deposit accounts related to irrevocable standby letters of credit. As of March 31, 2021, restricted cash classified as a current asset included \$75.0 million held in escrow for the purpose of fulfilling certain indemnification obligations. The full escrow amount of \$75.0 million was disbursed to the Company in June 2021.

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):

	<u>March 31, 2022</u>	<u>March 31, 2021</u>
Cash and cash equivalents	\$ 2,060,400	\$ 2,055,044
Restricted cash	13,634	86,632
Cash, cash equivalents and restricted cash	<u>\$ 2,074,034</u>	<u>\$ 2,141,676</u>

**(E) Contingencies**

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

**(F) 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:

<u>Property and Equipment</u>	<u>Estimated Useful Life</u>
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.

### **(G) Investments**

Investments in equity securities may be accounted for using (i) the fair value option if elected, (ii) fair value through earnings if fair value is readily determinable or (iii) for equity investments without readily determinable fair values, the measurement alternative to measure at cost adjusted for any impairment and observable price changes, as applicable. The election to use the measurement alternative is made for each eligible investment.

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

### **(H) Research and Development Expenses**

Research and development ("R&D") costs are expensed as incurred. Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. R&D costs primarily consist of costs associated with preclinical studies and clinical trials, including amounts paid to contract research organizations, contract manufacturing organizations, and other third parties that conduct R&D activities on behalf of the Company, as well as employee-related expenses, such as salaries, share-based compensation, and benefits, for employees engaged in R&D activities.

### **(I) Acquired In-Process Research and Development Expenses**

For the year ended March 31, 2022, the Company began reporting acquired in-process research and development ("IPR&D") expense as a separate line item in its consolidated statements of operations. Acquired IPR&D expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. These expenses were previously recorded in "Research and development" on the consolidated statements of operations. Prior periods have been revised to conform to the current period presentation.

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

### **(J) General and Administrative Expenses**

General and administrative ("G&A") expenses consist primarily of employee-related expenses for G&A personnel, including those responsible for the identification and acquisition or in-license of new drug candidates as well as for overseeing Vant operations and facilitating the use of the Company's platform and technologies at Vants. G&A expenses also consist of legal and accounting fees, consulting services and other operating costs

relating to corporate matters and daily operations. G&A expenses include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates along with costs incurred relating to the integration of new technologies.

#### **(K) Leases**

The Company determines if an arrangement includes a lease at the inception of the agreement. 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. Operating lease right-of-use assets and operating 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 operating 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 is any lease 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 economic factors present as of the lease commencement date.

#### **(L) 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, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable. 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.

#### **(M) Share-Based Compensation**

Share-based awards to employees, directors, and consultants, including stock options, restricted stock units, performance options and capped value appreciation rights, 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. 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 expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. 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. Prior to the closing of its business combination with MAAC, as a privately held company, the Company estimated the fair value of the shares of common stock underlying its share-based awards on each grant date. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common shares. The estimation of the fair value of the common shares considered factors including the following: the prices of the Company's common shares sold to investors in arm's length transactions; the estimated present value of the Company's future cash flows; the Company's business, financial condition and results of operations; the Company's forecasted operating performance; the illiquid nature of the Company's common shares; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions.

The Company applies a similar methodology to estimate the fair value of the shares of common stock underlying share-based awards issued by its privately held Vants. Following the closing of the Company's business combination with MAAC, RSL's common shares became publicly traded and the Company began determining 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. Therefore, it will not be necessary to determine the fair value of the new stock-based award pursuant to the methodology described above.

#### **(N) Fair Value Measurements**

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs

are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

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

The Company's financial instruments include shares of common stock of Arbutus Biopharma Corporation ("Arbutus"); shares of common stock of Sio Gene Therapies Inc. ("Sio"); shares of common stock of Heracles Parent, L.L.C., the parent entity of Datavant (as defined and discussed in Note 4, "Investments"); liability instruments issued, including the Roivant Warrants and Earn-Out Shares (each as defined in Note 3, "Business Combination with MAAC") liabilities issued in connection with the Company's business combination with MAAC (as discussed in Note 3, "Business Combination with MAAC"); the deferred consideration liability; its investments in other entities; cash and cash equivalents consisting of money market funds; accounts payable; and long-term debt.

The shares of Arbutus and Sio common stock and investments in common stock with a readily determinable fair value are classified as Level 1, and their fair value is determined based upon quoted market prices in an active market. In October 2021, shares of Arbutus' Series A participating convertible preferred shares ("Arbutus Preferred Shares") held by the Company were converted into shares of common stock of Arbutus pursuant to mandatory conversion provisions. Prior to conversion, the Arbutus Preferred Shares held by the Company were classified as Level 2 as the fair value of such preferred shares was determined based upon the quoted market price of Arbutus common stock into which such preferred shares were convertible. The shares of common stock of Heracles Parent, L.L.C., the parent entity of Datavant (as defined and discussed in Note 4, "Investments"), and liability instruments issued, excluding the Public Warrants (as defined and discussed in Note 3, "Business Combination with MAAC"), are classified as Level 3 within the fair value hierarchy as the assumptions and estimates used in the valuations are unobservable in the market. The Public Warrants are publicly traded and therefore are classified as Level 1 as the Public Warrants have a readily determinable fair value. Cash, accounts payable, and the deferred consideration liability are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The deferred consideration liability was based on a fixed monetary amount, and payment was based solely on the passage of time. The deferred consideration liability was settled in November 2021 by payment of \$50.0 million in cash as well as the issuance of 6,348,057 of the Company's common shares. Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. The carrying value of long-term debt issued by Dermavant Sciences Ltd. (together with its wholly owned subsidiaries, "Dermavant"), which is stated at amortized cost, approximates fair value based on current interest rates for similar types of borrowings and therefore is included in Level 2 of the fair value hierarchy. Long-term debt issued by Dermavant for which the

fair value option has been elected is included in Level 3 of the fair value hierarchy as the assumptions and estimates used in the valuation are unobservable in the market.

### **(O) Foreign Currency**

Assets and liabilities of foreign operations are translated using exchange rates in effect at the balance sheet date and their results of operations are translated using average exchange rates for the year. Certain transactions of the Company and its subsidiaries are denominated in currencies other than their functional currency. Adjustments resulting from the translation of the financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholders' equity. Foreign exchange transaction gains and losses are included in "Other expense, net" in the Company's statements of operations.

### **(P) 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 transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

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

recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Revenue is also generated by certain technology-focused Vants from subscription and service-based fees recognized for the use of certain technology developed by these Vants. 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, 2022 and 2021. Trade receivables, net is included in "Other current assets" on the accompanying consolidated balance sheets.

#### **(Q) Warrant Liabilities**

The Company classifies the Roivant Warrants as liabilities. At the end of each reporting period, changes in fair value during the period are recognized within the consolidated statements of operations. The Company will continue to adjust the carrying value of the liability associated with the Roivant Warrants for changes in the fair value until the earlier of a) the exercise or expiration of the Roivant Warrants or b) the redemption of the Roivant Warrants. Issuance costs incurred that were attributable to the Roivant Warrants were expensed as incurred.

#### **(R) Recently Adopted Accounting Pronouncements**

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU No. 2020-06"). ASU No. 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP. ASU No. 2020-06 also removes certain settlement conditions that are required for equity contracts to qualify for the derivatives scope exception, which will permit more equity contracts to qualify for it. Either a modified retrospective transition method or a fully retrospective transition method is permissible for the adoption of this standard. ASU No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The early-adoption of ASU No. 2020-06 on April 1, 2021 did not have a material impact on the Company's consolidated financial statements.

#### **Note 3—Business Combination with MAAC**

On September 30, 2021 (the "Closing Date"), in accordance with the Business Combination Agreement, as amended (the "Business Combination Agreement"), RSL completed its previously announced business combination (the "Business Combination") with MAAC, through the merger of RSL's wholly owned subsidiary, Rhine Merger Sub, Inc., with MAAC (the "Merger"), with MAAC surviving the Merger as a wholly owned subsidiary of RSL. As MAAC does not represent a business for accounting purposes and its primary asset represents cash and cash equivalents, the Business Combination was treated as an equity contribution in exchange for the issuance of RSL shares. The net assets of MAAC were stated at historical cost, with no goodwill or other intangible assets recorded. Reported amounts from operations included herein prior to the Business Combination are those of RSL.

On the Closing Date prior to the effective time of the Merger (the “Effective Time”), RSL effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. The shares, equity awards and net loss per share available to holders of the Company’s common stock prior to the Business Combination, have been retroactively restated to reflect the fixed exchange ratio.

In accordance with the terms of the Business Combination Agreement, at the Effective Time:

- a. each share of MAAC Class A common stock (the “MAAC Class A Shares”) and each share of MAAC Class B common stock (the “MAAC Class B Shares”) that were outstanding immediately before the Effective Time (other than treasury shares and any shares held by Patient Square Capital LLC (the “MAAC Sponsor”), any affiliate of the MAAC Sponsor or any of MAAC’s independent directors (the “MAAC Independent Directors”) or its transferee) were automatically canceled and extinguished and converted into one common share of RSL (the “Roivant Common Share”),
- b. each MAAC Class B Share that was outstanding immediately before the Effective Time and held by the MAAC Sponsor, any affiliate of the MAAC Sponsor or any of the MAAC Independent Directors or its transferee were automatically canceled and extinguished and converted into a number of Roivant Common Shares based on an exchange ratio of 0.75, with a portion of such Roivant Common Shares issued to the MAAC Sponsor, any affiliate of the MAAC Sponsor, any MAAC Independent Director or its transferee by virtue of the Merger being subject to the vesting and other terms and conditions set forth in the Sponsor Support Agreement (as more fully described below),
- c. each warrant to purchase MAAC Class A Shares that was outstanding immediately before the Effective Time was converted automatically into a right to acquire a Roivant Common Share (a “Roivant Warrant”) at an exercise price of \$11.50 per share, subject to certain adjustments.

Following the Merger, the Roivant Common Shares and the Roivant Warrants began trading on the Nasdaq Global Market under the ticker symbols “ROIV” and “ROIVW,” respectively, on October 1, 2021.

In connection with the Business Combination, RSL entered into subscription agreements with certain investors, whereby it issued 22,000,000 common shares at \$10.00 per share for an aggregate purchase price of \$220.0 million (the “PIPE Financing”). The PIPE Financing closed simultaneously with the consummation of the Business Combination.

In connection with the Business Combination and PIPE Financing, the Company received \$213.4 million in cash at closing (the “Closing”), net of deferred underwriting expenses and unpaid expenses incurred by MAAC in connection with the transaction. The Company incurred \$24.4 million in costs directly related to the Business Combination and PIPE Financing, such as banker fees and costs associated with third-party legal, accounting and other professional services. Upon Closing, these costs, which had been capitalized on the Company’s balance sheet were recorded as a reduction of additional paid-in capital with the exception of \$7.4 million, which were expensed as they represent the allocation of the transaction costs associated with the Roivant Warrants and Earn-Out Shares liabilities. Transaction costs were allocated to the Roivant Warrants and Earn-Out Shares liabilities based on the fair value of such instruments out of the total consideration.

### ***Sponsor Support Agreement***

Concurrently with the execution of the Business Combination Agreement, MAAC, the MAAC Sponsor, Roivant and each of the MAAC Independent Directors, entered into the Sponsor Support Agreement, which was subsequently amended on June 9, 2021, to reflect the MAAC Independent Directors and Roivant entering into respective Lock-Up Agreements, and further amended on September 30, 2021.

Pursuant to the Sponsor Support Agreement, among other things:

- a. 2,033,591 Roivant Common Shares issued to the MAAC Sponsor and 10,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the “20% Earn-Out Shares”), each in respect



of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to \$15.00 over any twenty out of thirty trading day period during the Vesting Period (defined below).

- b. 1,016,796 Roivant Common Shares issued to the MAAC Sponsor and 5,000 Roivant Common Shares issued to each MAAC Independent Director (collectively, the “10% Earn-Out Shares” and, together with the 20% Earn-Out Shares, the “Earn-Out Shares”), each in respect of its MAAC Class B Shares, will vest if the closing price of Roivant Common Shares is greater than or equal to \$20.00 over any twenty out of thirty trading day period during the Vesting Period (as defined below).
- c. The remaining number of Roivant Common Shares issued to the MAAC Sponsor and each MAAC Independent Director are not subject to the vesting conditions described above (the “Retained Shares”).

The Vesting Period represents the period commencing on November 9, 2021, the date on which the registration statement on Form S-1 required to be filed by the Company in connection with the PIPE Financing was declared effective, and ending no later than September 30, 2026 (the “Vesting Period”). The Vesting Period will, if a definitive purchase agreement with respect to a Sale (as defined in the Sponsor Support Agreement) is entered into on or prior to the end of such period, be extended to the earlier of one day after the consummation of such Sale and the termination of such definitive transaction agreement, and if a Sale occurs during such Vesting Period, then all of the Earn-Out Shares unvested as of such time will automatically vest immediately prior to the consummation of such Sale. If any Earn-Out Shares have not vested on or prior to the end of such Vesting Period, then such Earn-Out Shares will be forfeited.

The Earn-Out Shares require liability classification and are classified as “Liability instruments measured at fair value” on the consolidated balance sheets. The Earn-Out Shares liability is subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company’s statement of operations.

### ***Lock-Up Agreements***

On May 1, 2021 and June 9, 2021, RSL, on the one hand, and the MAAC Sponsor, the MAAC Independent Directors and certain Roivant equityholders, on the other hand, entered into lock-up agreements, pursuant to which, among other things, the MAAC Sponsor, the MAAC Independent Directors and such Roivant equityholders have agreed not to effect any sale or distribution of the Roivant Common Shares (including those underlying incentive equity awards or Roivant Warrants) held by the MAAC Sponsor, the MAAC Independent Directors or such equityholders as of immediately following the Closing during the applicable lock-up period, subject to customary exceptions.

The lock-up period applicable to Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors as of immediately following the Closing will be (i) with respect to 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, six months following the Closing, which expired on March 30, 2022, (ii) with respect to an additional 25% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, the earlier of twelve months following the achievement of certain price-based vesting restrictions or six years from the Closing and (iii) with respect to 50% of the Roivant Common Shares held by the MAAC Sponsor and MAAC Independent Directors, thirty-six months following the Closing.

The Roivant Common Shares underlying warrants held by the MAAC Sponsor as of immediately following the Closing will be subject to a corresponding lock-up period for (a) with respect to 25% of such warrants held by the MAAC Sponsor, six months from the Closing, which expired on March 30, 2022, (b) with respect to an additional 25% of such warrants held by the MAAC Sponsor, twelve months from Closing and (c) with respect to 50% of such warrants held by the MAAC Sponsor, thirty-six months from the Closing.

The lock-up period applicable to Roivant Common Shares held by certain Roivant equityholders as of immediately following the Closing (including those underlying incentive equity awards) will be (x) with respect

to 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), six months following the Closing, which expired on March 30, 2022, (y) with respect to an additional 25% of the Roivant Common Shares held by such Roivant equityholders (including those underlying incentive equity awards), twelve months following the Closing and (z) with respect to 50% of the Roivant Common Shares (including those underlying incentive equity awards) held by such Roivant equityholders, thirty-six months following the Closing.

### ***Common Stock Warrants***

At the effective time of the Merger, 10,214,365 Roivant Warrants that were held by the MAAC Sponsor at an exercise price of \$11.50 (the “Private Placement Warrants”) and 20,535,896 Roivant Warrants held by MAAC’s shareholders at an exercise price of \$11.50 (the “Public Warrants”) were converted into the right to acquire Roivant Common Shares. Pursuant to the agreement governing the Roivant Warrants, the Roivant Warrants became exercisable 30 days following the completion of the Business Combination. The Roivant Warrants will expire five years after the completion of the Business Combination, or earlier upon redemption or liquidation.

The Private Placement Warrants are generally identical to the Public Warrants, except that (i) the Private Placement Warrants (including the common stock issuable upon exercise of the Private Placement Warrants) were not transferable, assignable or salable until 30 days after the completion of the Business Combination (ii) they will not be redeemable by the Company when the price per share of Roivant Common Shares equals or exceeds \$18.00, and (iii) the Private Placement Warrants may be exercised by holders on a cashless basis. If the Private Placement Warrants are held by holders other than our sponsor or its permitted transferees, the Private Placement Warrants will be redeemable by Roivant in all redemption scenarios and exercisable by the holders on the same basis as the Public Warrants.

The Roivant Warrants require liability classification and are classified as “Liability instruments measured at fair value” on the consolidated balance sheets. The Private Placement Warrants liability and Public Warrants liability are subject to remeasurement at each balance sheet date with changes in fair value recognized in the Company’s statement of operations. As of March 31, 2022, 60,021 Roivant Warrants have been exercised and none redeemed.

### ***Redemption of Roivant Warrants when the price per share of Roivant Common Shares equals or exceeds \$18.00.***

The Company may redeem the outstanding Roivant Warrants for cash (except with respect to the Private Placement Warrants):

- in whole and not in part;
- at a price of \$0.01 per Roivant Warrant;
- upon a minimum of 30 days’ prior written notice of redemption; and
- if, and only if, the last reported sale price of common stock for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which the Company sends the notice of redemption to the warrant holders (the “Reference Value”) equals or exceeds \$18.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like).

However, in this case, the Company will not redeem the Roivant Warrants unless an effective registration statement under the Securities Act covering the Roivant Common Shares issuable upon exercise of the Roivant Warrants is effective and a current prospectus relating to those Roivant Common Shares is available throughout the 30-day redemption period. Any such exercise would not be on a “cashless” basis and would require the exercising warrant holder to pay the exercise price for each Roivant Warrant being exercised.

The Company may redeem the outstanding Roivant Warrants (except as described herein with respect to the Private Placement Warrants):

- in whole and not in part;
- at \$0.10 per Roivant Warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their Roivant Warrants on a cashless basis prior to redemption and receive that number of Roivant Common Shares determined by reference to an agreed table based on the redemption date and the "fair market value" of the Roivant Common Shares;
- if, and only if, the Reference Value equals or exceeds \$10.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like); and
- if the Reference Value is less than \$18.00 per share (as adjusted for stock splits, stock dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like), the Private Placement Warrants must also concurrently be called for redemption on the same terms (except as described herein with respect to a holder's ability to cashless exercise its warrants) as the outstanding Public Warrants, as described above.

For these purposes, "fair market value" of Roivant Common Shares shall mean the volume-weighted average price of common shares for the 10 trading days immediately following the date on which the notice of redemption is sent to warrant holders. In no event will the Roivant Warrants be exercisable in connection with this redemption feature for more than 0.361 Roivant Common Shares per Roivant Warrant (subject to adjustment).

#### **Note 4—Investments**

##### *Investment in Arbutus*

In October 2017, pursuant to a subscription agreement entered into by RSL and Arbutus, RSL acquired 16,013,540 shares of common stock of Arbutus and 1,164,000 Arbutus Preferred Shares, which converted into 22,833,922 shares of Arbutus common stock in October 2021. The Company accounts for its investment in Arbutus as an equity method investment accounted for using the fair value option. Due to the Company's significant influence over operating and financial policies, Arbutus is considered a related party of the Company. At March 31, 2022, RSL held approximately 26% of issued and outstanding shares of Arbutus.

At March 31, 2022 and 2021, the aggregate fair value of the Company's investment in Arbutus was \$115.8 million and \$129.4 million, respectively, with the Company recognizing an unrealized loss on its investment in Arbutus of \$13.6 million and an unrealized gain of \$90.2 million in the accompanying consolidated statements of operations for the years ended March 31, 2022 and 2021. The fair value of the Company's investment was determined using the closing price of Arbutus's common stock on March 31, 2022 and 2021 of \$2.98 and \$3.33, respectively.

##### *Investment in Sio*

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

At March 31, 2022 and 2021, the fair value of the Company's investment in Sio was \$12.4 million and \$48.5 million, respectively, with the Company recognizing an unrealized loss on its investment in Sio of \$36.1 million and an unrealized gain of \$3.2 million in the accompanying consolidated statements of operations for the years ended March 31, 2022 and 2021, respectively. The fair value of common shares held by the Company was determined using the closing price of Sio's common stock on March 31, 2022 and 2021 of \$0.67 and \$2.61, respectively.

### *Investment in Datavant*

In April 2020, following an equity raise completed by Datavant Holdings, Inc. (“Datavant”) along with a restructuring of Datavant’s equity classes, it was determined that RSL no longer controlled Datavant. As such, the Company deconsolidated Datavant as of April 2020. Due to the Company’s significant influence over operating and financial policies, Datavant is considered a related party of the Company. Upon deconsolidation, the Company recorded its investment in Datavant based on the fair value of Datavant preferred shares held of \$99.0 million. Prior to the Datavant Merger (defined below), the Company accounted for its investment in Datavant using the measurement alternative to fair value. Under the measurement alternative, the investment is remeasured upon observable price changes in orderly transactions or upon impairment, if any. The Company recognized a gain on deconsolidation of \$86.5 million in the accompanying consolidated statements of operations for the year ended March 31, 2021. In July 2020, Datavant issued and sold additional preferred shares to RSL at a price consistent with that of the initial round of Datavant’s Series B equity raise, which resulted in an increase in the carrying value of the Company’s investment to \$100.6 million.

In June 2021, Datavant and Heracles Parent, L.L.C. (referred to herein as “Ciox Parent” and, after the closing of the Datavant Merger (as defined below), “Datavant”), a provider of healthcare information services and technology solutions to hospitals, health systems, physician practices and authorized recipients of protected health records in the United States, primarily through its wholly owned subsidiary CIOX Health, LLC, entered into a definitive agreement to merge Datavant with and into a newly formed wholly owned subsidiary of Ciox Parent (the “Datavant Merger”). The merger closed on July 27, 2021. At closing, the Company received approximately \$320 million in cash and a minority equity stake in Ciox Parent. As a result of the transaction, the Company recognized a gain on remeasurement of \$443.8 million in the accompanying consolidated statements of operations for the year ended March 31, 2022. As of March 31, 2022, the Company’s minority equity interest represented approximately 17% of the outstanding Class A units in Ciox Parent. Ciox Parent’s capital structure includes several classes of preferred units that, among other features, have liquidation preferences and conversion features. Upon conversion of such preferred units into Class A units, the Company’s ownership interest would be diluted.

Following the completion of the Datavant Merger, the Company’s minority equity interest became subject to the equity method of accounting. At such time, the fair value option was elected to continuously remeasure the investment to fair value each reporting period with changes in fair value reflected in earnings. As of March 31, 2022 and July 27, 2021, the fair value of the Company’s investment was \$193.9 million and \$224.1 million, respectively, with the Company recognizing an unrealized loss on its investment of \$30.2 million for the year ended March 31, 2022. The fair value of the Company’s investment was determined using valuation models that incorporate significant unobservable inputs and is classified as a Level 3 measurement within the fair value hierarchy. Refer to Note 14, “Fair Value Measurements” for more information.

### *Other Investment*

The Company holds an additional equity investment that is measured using the fair value option. The fair value of this investment was \$3.7 million and \$11.1 million as of March 31, 2022 and 2021, respectively.

### **Note 5—Asset Acquisitions and License Agreements**

During the years ended March 31, 2022 and 2021, the Company, directly or indirectly through Vants, completed the following key asset acquisitions and license agreements. The Company evaluated the below agreements, except the collaboration agreement entered into between Proteovant Therapeutics, Inc. and Blueprint Medicines Corporation (“Blueprint Medicines”) that is evaluated separately below, and determined that the acquired assets did not meet the definition of a business as substantially all the fair value of the assets acquired were concentrated in a single asset or group of similar assets and/or the acquired assets were not capable of producing outputs due to the lack of an assembled workforce and early stage of development and thus, each transaction was accounted for as an asset acquisition.

The Company then evaluated whether each in-process research and development asset had an alternative future use and concluded it did not. As a result, the Company recorded the consideration attributable to in-process research and development under the below agreements as acquired in-process research and development expense in the accompanying consolidated statements of operations for the years ended March 31, 2022 and 2021.

### ***Genevant***

In July 2020, RSL increased its investment in Genevant Sciences Ltd. (“Genevant”) as part of a recapitalization transaction (the “Recapitalization”). Genevant, an entity focused on the discovery, development, and commercialization of a broad range of RNA-based therapeutics enabled by Arbutus’ proprietary lipid nanoparticle and ligand conjugate delivery technologies, was created in April 2018 as part of an agreement between RSL and Arbutus. As part of the initial transaction entered into in April 2018, RSL contributed \$38.7 million in cash, including transaction costs, for an equity ownership interest in Genevant. Prior to the Recapitalization, RSL accounted for its investment in Genevant under the equity method of accounting as it had determined that it was not the primary beneficiary of Genevant since it did not have the power to direct its most significant activities. Additionally, RSL made additional investments in the form of promissory notes issued by Genevant amounting to \$20.1 million aggregate principal amount outstanding (the “Genevant Outstanding Notes”) prior to the Recapitalization. RSL applied its share of losses relating to its equity method investment in Genevant against the Company’s carrying value of its investment in Genevant’s common shares and against the carrying value of the Genevant Outstanding Notes. The carrying value of RSL’s investment in Genevant was reduced to zero prior to the Recapitalization.

Pursuant to the Recapitalization, the following transactions were completed:

- Genevant issued 74,272,043 common shares to RSL for an aggregated purchase price of \$20.5 million;
- \$15.1 million aggregate principal amount of the Genevant Outstanding Notes were converted into 54,526,549 common shares; and
- Genevant issued 9,057,566 common shares to Arbutus for an aggregated purchase price of \$2.5 million.

Following the Recapitalization, RSL held an 82.9% controlling interest in Genevant.

Concurrent with the Recapitalization, the composition of Genevant’s Board of Directors was restructured to include two directors designated by RSL and one director who is a senior officer of Genevant.

As a result of the Recapitalization and changes to the bye-laws, RSL determined that it controls the most significant activities of Genevant and is the primary beneficiary of Genevant following the Recapitalization. As such, RSL began consolidating Genevant into the Company’s consolidated financial statements from the date of the Recapitalization. The Company evaluated the acquired set of assets and activities and determined that the acquired set did not meet the definition of a business and thus the transaction was not considered a business combination.

The transactions completed as part of the Recapitalization represent an acquisition achieved in stages, which required the remeasurement of RSL’s previously held interest in Genevant. As such, RSL’s investments in Genevant were remeasured to fair value of \$28.8 million, also resulting in a gain of \$28.8 million that was recognized in the accompanying consolidated statements of operations for the year ended March 31, 2021. Along with the fair value of noncontrolling interests in Genevant of \$9.2 million and cash paid of \$20.5 million for common shares of Genevant as part of the Recapitalization, total consideration paid was \$58.5 million. Of this amount, \$41.4 million was attributed to in-process research and development, which was determined by the Company to have not reached technological feasibility and therefore have no alternative future use. Accordingly, the Company recorded \$41.4 million as acquired in-process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2021.

## ***Proteovant***

In November 2020, Proteovant Sciences, Inc. (formerly known as Pharmavant 5, Inc.) (together with its wholly owned subsidiaries, “Proteovant”) entered into a stock purchase agreement to acquire Oncopia Therapeutics, Inc. (“Oncopia”), a preclinical biotechnology company developing small molecule protein degraders primarily against certain oncology targets. Upfront proceeds to Oncopia’s shareholders were \$105.0 million, prior to certain adjustments in accordance with the terms of the agreement. Proteovant is also obligated to make future development and commercial milestone payments of up to \$100.0 million for the first product targeting each of the two specified initial targets, and up to \$51.0 million for the first product targeting each of certain specified additional molecular targets. Additionally, the Company’s investments in promissory notes issued by Oncopia for an aggregate principal amount of \$11.5 million were settled through either conversion to equity or cancellation.

Oncopia’s intellectual property was developed by the University of Michigan laboratory run by Oncopia’s co-founder (the “Co-Founder”). In connection with Proteovant’s acquisition, Oncopia amended and restated its existing license agreements with the University of Michigan. Under the new license agreement, Oncopia will be obligated to make future development and commercial milestone payments of up to \$8.6 million for the first product for each molecular target covered by intellectual property included in the agreement, in addition to paying tiered royalties on net sales ranging from low- to mid-single digits, subject to certain adjustments.

The Co-Founder’s lab at the University of Michigan had been providing on-going discovery and optimization services to Oncopia under a sponsored research agreement (the “SRA”). Immediately after closing the acquisition, Oncopia extended the SRA through at least December 31, 2023, and expanded the potential molecular targets to be pursued under the SRA. As revised, Oncopia is obligated to pay the University of Michigan approximately \$15.5 million under the SRA.

Lastly, in connection with the acquisition of Oncopia, the Co-Founder entered into an agreement with the Company to serve as a consultant. In exchange for these services, the Company has agreed to grant the Co-Founder RSL restricted stock units for which the majority will vest upon achievement of development milestones for products directed to targets for which no milestones are payable to Oncopia shareholders and the remaining portion will be subject to time-based service requirements. These restricted stock units were also subject to a liquidity requirement to vest, which was achieved upon the closing of the Business Combination. The Company will also make a cash payment to the Co-Founder upon achievement of development milestones for each such product.

During the year ended March 31, 2021, the Company recorded \$116.5 million, relating to the net upfront cash payment of \$101.2 million, settlement of promissory notes receivable, including accrued interest, of \$11.9 million, and fair value of future contingent consideration payments of \$3.4 million, as acquired in-process research and development expense in the accompanying consolidated statements of operations.

In December 2020, RSL, Proteovant and SK, Inc. (formerly known as SK Holdings Co., Ltd.) (“SK”) entered into a subscription agreement (the “Subscription Agreement”) pursuant to which SK agreed to make a \$200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date. In January 2021, in accordance with the terms of the Subscription Agreement, SK made the first payment of \$100.0 million to Proteovant. SK made the second payment of \$100.0 million to Proteovant in July 2021.

In February 2022, Proteovant entered into a collaboration agreement with Blueprint Medicines pursuant to which the parties will jointly research and advance up to two novel protein degrader compounds into development candidates, as well as up to two additional novel protein degrader target programs as may be mutually agreed to by the Blueprint Medicines and Proteovant (each a target program). Under the terms of the collaboration agreement, Proteovant received a nonrefundable, upfront payment of \$20.0 million in March 2022 and will be eligible to receive up to an additional \$632.0 million in contingent milestone payments including

specified research, development, regulatory and commercialization milestones and tiered percentage royalties on a licensed product-by-licensed product basis ranging from the mid- to high-single digits on net sales on the first two target programs, subject to adjustment in specified circumstances. If Proteovant opts-in to the second target program (the “Opt-In Right”), the parties will jointly develop and commercialize such compounds and will split profits and losses of that program equally in the United States along with global development costs. Additionally, development and regulatory milestone payments for the second target or opt-in target program will be reduced, and Proteovant will only be eligible to receive commercialization milestone payments and royalties on ex-United States sales of products relating to such target program. In addition, the parties may jointly extend the collaboration, with the same structure and financial terms, for up to two additional target programs through additional funding by Blueprint Medicines and Proteovant’s Opt-In Right would extend to the second of such additional target programs.

Proteovant will be performing research and development activities throughout the period until Blueprint Medicines can exercise its option to obtain a worldwide, exclusive license to develop and commercialize any licensed compound, subject to Proteovant’s Opt-In Right. Proteovant initially recorded the \$20.0 million upfront payment as deferred revenue on the accompanying consolidated financial statements and will recognize it as revenue as the services are provided.

### *Affivant*

In November 2020, RSL and its indirect subsidiary Affivant Sciences GmbH (“Affivant”) entered into a licensing and strategic collaboration agreement with Affimed N.V. (“Affimed”) to develop and commercialize novel innate cell engagers for multiple cancer targets in exchange for consideration that includes \$40.0 million in upfront cash and pre-paid R&D funding and \$20.0 million of newly issued shares in RSL. Affimed could receive further short-term proceeds in the form of option fees contingent on the commencement of additional programs contemplated under the agreement. Affimed is eligible to receive up to an additional approximately \$2.0 billion in milestones over time upon achievement of specified development, regulatory and commercial milestones, as well as tiered royalties on net sales.

### *Acquisition of Silicon Therapeutics*

In March 2021, the Company completed the acquisition of the business of Silicon Therapeutics, LLC (“Silicon Therapeutics”), a physics-driven computational drug discovery company, for total consideration of approximately \$450.0 million, with additional cash payments payable subject to the satisfaction of certain regulatory and commercial milestones. This acquisition did not include one of Silicon Therapeutics’ subsidiaries, Silicon SWAT, Inc. Approximately \$350.0 million of the consideration was payable primarily in the Company’s common stock at or near closing of the acquisition (the “First Tranche”). At closing of the acquisition, the Company issued 21,409,764 common shares and paid approximately \$14.0 million in cash, net of cash received, to Silicon Therapeutics after giving effect to certain transaction adjustments and holdbacks. The remainder of the First Tranche was paid in a combination of common shares and cash as certain holdbacks were released. In November 2021, the Company transferred the remaining \$100.0 million (the “Second Tranche Consideration”) to Silicon Therapeutics through a \$50.0 million cash payment and the issuance of 6,348,057 of the Company’s common shares.

The transaction was accounted for as an asset acquisition as substantially all of the fair value of the assets acquired were concentrated in a single asset, in-process research and development related to the computational drug discovery platform that designs and develops small molecule therapeutics. For accounting purposes, the fair value of consideration transferred was \$402.4 million, consisting of \$281.7 million relating to the fair value of common shares issued upfront and expected to be issued shortly thereafter; \$105.1 million relating to the fair value of liabilities due to the sellers, including the Second Tranche Consideration, future contingent consideration payments, and closing consideration to be paid in cash; and cash of \$15.6 million paid at closing. Of this amount, \$399.6 million was attributed to in-process research and development, which was determined to

have no alternative future use. Accordingly, the Company recorded \$399.6 million as acquired in-process research and development expense in the accompanying consolidated statement of operations for the year ended March 31, 2021.

In connection with the transaction, the vesting of certain outstanding Silicon Therapeutics share-based compensation awards held by employees of Silicon Therapeutics was discretionarily accelerated at closing. As a result, the Company recorded share-based compensation expense of \$23.5 million in the accompanying consolidated statements of operations for the year ended March 31, 2021.

In addition, certain share-based compensation awards of Silicon Therapeutics were exchanged with restricted common stock of the Company, subject to certain service-based vesting requirements, with a fair value of \$22.6 million. Of this amount, \$15.6 million was attributed to precombination service and therefore included in the total fair value of consideration transferred.

### ***Priovant***

In September 2021, Priovant Therapeutics, Inc. (“Priovant”) entered into a license and collaboration agreement with Pfizer, Inc. (“Pfizer”) (the “Pfizer License Agreement”). The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The fair value of consideration transferred was \$82.1 million, consisting of \$70.0 million of preferred stock issued to Pfizer, representing a dilution-protected minority ownership interest in Priovant; a \$10.0 million upfront cash payment; and \$2.1 million relating to other obligations. The acquired rights, which included the licensed rights, starting materials and in-process inventory for each drug candidate, represent in-process research and development assets, which were determined to have no alternative future use. Accordingly, the Company recorded \$82.1 million as acquired in-process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2022.

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 sales 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.

### ***Hemavant***

In November 2021, Hemavant Sciences GmbH (“Hemavant”), a wholly owned subsidiary of the Company, entered into a license agreement with Eisai Co., Ltd. (“Eisai”) (the “Eisai License Agreement”). Pursuant to the Eisai License Agreement, Eisai granted Hemavant (i) an exclusive, worldwide, sublicensable, royalty-bearing license under certain patents and know-how and (ii) a non-exclusive, worldwide, sublicensable, royalty-bearing license under certain additional patents, know-how and inventions, in each case, to develop, manufacture and commercialize the compound known as RVT-2001 and products incorporating RVT-2001 for all human and animal uses. In exchange for the rights, the Company made an upfront payment to Eisai consisting of \$8.0 million in cash and the issuance of \$7.0 million in shares of the Company’s common stock at an agreed price of \$8.00 per share. Hemavant may also be obligated to pay up to a maximum of \$65.0 million in development and regulatory milestone payments (with respect to the product for the first indication) and up to a maximum of \$18.0 million in payments (with respect to the product for each additional indication) and up to a maximum of \$295.0 million in commercial milestone payments. Hemavant may also be obligated to pay a tiered high single-digit to sub-teens royalty, subject to certain customary reductions, on net sales of licensed products.



The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The acquired rights, which include the licensed rights and in-process inventory of the drug candidate, represent in-process research and development assets that were determined to have no alternative future use. The fair value of the 874,957 shares of the Company's common stock issued to Eisai based on the closing price as of the effective date of the Eisai License Agreement was \$6.1 million. Accordingly, the Company recorded \$14.1 million as acquired in-process research and development expense in the accompanying consolidated statements of operations for the year ended March 31, 2022.

#### Note 6—Accrued Expenses

Accrued expenses at March 31, 2022 and 2021 consisted of the following (in thousands):

	March 31, 2022	March 31, 2021
Research and development expenses	\$ 66,188	\$ 20,755
Compensation-related expenses	44,262	38,552
Other general and administrative expenses	17,081	17,629
Total accrued expenses	<u>\$ 127,531</u>	<u>\$ 76,936</u>

#### Note 7—Long-Term Debt and Loan Commitment

##### (A) Long-Term Debt

Long-term debt, net consists of the following (in thousands):

	March 31, 2022	March 31, 2021
Principal amount	\$217,400	\$170,100
Exit fee / end of term charge	5,000	1,390
Less: unamortized debt discount and issuance costs	(12,375)	(1,210)
Total debt, net	210,025	170,280
Less: current portion	—	—
Total long-term debt, net	<u>\$210,025</u>	<u>\$170,280</u>

#### *Dermavant*

In May 2019, Dermavant entered into a loan and security agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules"), pursuant to which Dermavant borrowed an aggregate of \$20.0 million, which bore interest at a variable per annum rate at the greater of (i) 9.95% or (ii) the prime rate plus 4.45%. Dermavant was also obligated to pay an end of term charge of \$1.4 million. Following the achievement of certain milestones, the term loan maturity was extended to June 1, 2023 with interest-only monthly payments through December 2021. All amounts outstanding under the Hercules Loan Agreement were repaid in May 2021 using the proceeds from a \$40.0 million senior secured credit facility (the "Credit Facility") entered into by Dermavant and certain of its subsidiaries in May 2021 with XYQ Luxco S.A.R.L ("XYQ Luxco"), as lender, and U.S. Bank National Association, as collateral agent. The Credit Facility has a five-year maturity and bears an interest rate of 10.0% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter through the maturity date. A lump sum principal payment is due on the maturity date. Dermavant is also obligated to pay an exit fee of \$5.0 million. The exit fee can be reduced to \$4.0 million upon achievement of certain equity milestones defined in the agreement, which are not deemed likely as of March 31, 2022. In connection with the funding of the Credit Facility, Dermavant issued a warrant to XYQ Luxco to purchase 1,199,072 common shares of Dermavant at an exercise price of \$0.01 per common share.

In connection with Dermavant’s acquisition of tapinarof from GlaxoSmithKline Intellectual Property Development Ltd. and Glaxo Group Limited (collectively “GSK”) pursuant to an asset purchase agreement (the “GSK Agreement”), Dermavant and NovaQuest Co-Investment Fund VIII, L.P. (“NovaQuest”) entered into a funding agreement (the “NovaQuest Agreement”). Pursuant to the NovaQuest Agreement, Dermavant borrowed \$100.0 million in August 2018 and \$17.5 million in October 2018 in exchange for an obligation to make certain variable future payments calculated as a function of the achievement of regulatory and commercial milestones or events of termination. The aggregate maximum amount of regulatory milestone payments that Dermavant could be required to make under the NovaQuest Agreement is \$440.6 million, with \$176.3 million due over a six-year period paid quarterly following the U.S. regulatory approval of VTAMA in May 2022. The maximum aggregate amount of commercial milestone payments is \$141.0 million. In some circumstances, Dermavant may be able to offset certain of the regulatory milestone payments with up to \$88.1 million of the commercial milestone payments. At issuance, the Company concluded that certain features of the long-term debt would be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, the Company has elected the fair value option for this financial instrument and will record the changes in the fair value within the statements of operations at the end of each reporting period. Direct costs and fees related to the debt issued under the NovaQuest Agreement were recognized in earnings. As of March 31, 2022 and 2021, the fair value of the debt was \$177.4 million and \$150.1 million, respectively. Refer to Note 14, “Fair Value Measurements” for additional details regarding the fair value measurement.

**(B) Debt Maturities**

Annual maturities, including the exit fee, of debt outstanding as of March 31, 2022 are as follows (in thousands). Long term debt issued by Dermavant for which the fair value option has been elected is excluded from the below as the repayment terms are variable.

<u>Years Ending March 31,</u>	
2023	\$ —
2024	—
2025	—
2026	—
2027	45,000
Thereafter	—
Total	<u>\$ 45,000</u>

**(C) Loan Commitment**

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

VTAMA (tapinarof) cream was approved by the FDA in May 2022. Refer to Note 17, “Subsequent Events” for more information.

## **Note 8—Related Party Transactions**

### **Sumitomo Dainippon Pharma Co., Ltd.**

In May 2021, the Company entered into an Asset Purchase Agreement with Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (“SPC”) (the “Asset Purchase Agreement”). The transactions contemplated by the Asset Purchase Agreement closed in June 2021. Pursuant to the Asset Purchase Agreement: (i) Sumitomo terminated all of its existing options to acquire the Company’s equity interests in certain of its subsidiaries (the “Sumitomo Options”); (ii) the Company transferred and assigned to SPC all of its intellectual property, development and commercialization rights for (a) lefamulin in Mainland China, Taiwan, Hong Kong, and Macau (collectively “Greater China”), (b) vibegron in Mainland China, (c) rodatristat ethyl in Greater China and South Korea and (d) RVT-802 in Greater China and South Korea; (iii) Sumitomo agreed to pay the Company \$5.0 million in cash; and (iv) Sumitomo entered into an agreement with the Company to pursue future collaborations with Genevant. The Company received the cash payment, net of certain withholding taxes, in August 2021. The Company recorded a gain on the termination of the Sumitomo Options of \$66.5 million, consisting of the fair value of the Sumitomo Options on the date of termination and the cash payment, in the accompanying consolidated statements of operations for the year ended March 31, 2022.

### ***Transition Services Agreement and Strategic Cooperation Agreement***

In December 2019, RSL and Sumitomo completed the transactions contemplated by the transaction agreement by and between RSL and Sumitomo, dated as of October 31, 2019 (the “Sumitomo Transaction Agreement”). Concurrent with entry into the Sumitomo Transaction Agreement, RSL and Sumitomo entered into the following agreements: (i) a transition services agreement (the “TSA”), pursuant to which the parties agreed to provide certain transitional services to one another at cost for a specified period of time following the closing date and (ii) a strategic cooperation agreement (the “SCA”), providing for certain technology-related collaborations. Pursuant to the terms of the TSA and the SCA, RSL billed Sumitomo \$1.0 million and \$1.4 million, net of amounts billed by Sumitomo to RSL, during the years ended March 31, 2022 and 2021, respectively. Additionally, during each of the years ended March 31, 2022 and 2021, the Company paid Sumitomo a \$1.0 million DrugOme access fee pursuant to the SCA.

On March 1, 2022, RSL and Sumitomo amended the SCA. In connection with the amendment, RSL agreed to pay Sumitomo an aggregate of \$4.5 million. This consideration was expensed during the year ended March 31, 2022.

## **Note 9—Shareholders’ Equity**

### **(A) RSL Common Stock**

On September 30, 2021 in connection with the closing of the Business Combination, the Company effected a 2.9262-for-1 stock subdivision based on the fixed exchange ratio established in the Business Combination. All per share amounts and number of shares in the consolidated financial statements and related notes have been retroactively restated to reflect the stock split.

Additionally, in connection with the closing of the Business Combination, the Company adjusted its authorized share capital to equal 7,000,000,000 common shares, par value \$0.000000341740141 per share. Each common share has the right to one vote. The holders of common shares are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared by the board of directors since the Company’s inception.

## **(B) Committed Equity Facility**

On February 14, 2022, the Company entered into a committed equity facility (the “Facility”) with an affiliate of Cantor Fitzgerald & Co. (“Cantor”). Under the terms of the Facility, Cantor has committed to purchase up to an aggregate of \$250.0 million in the Company’s common shares from time to time at the request of the Company, subject to certain limitations and the satisfaction of certain conditions. Any sales of the Company’s common shares to Cantor under the Facility will be made at 99% of the volume-weighted average price of the Company’s common shares on Nasdaq on a given trading day. In consideration for entry into the Facility, the Company paid Cantor an upfront commitment fee in the form of 145,986 common shares. As of March 31, 2022, \$250.0 million of the Company’s common shares remained available for sale under the Facility.

## **(C) Consolidated Vant Equity Transactions**

### ***Immunovant***

In May 2020 and September 2020, Immunovant, Inc. achieved the first and second earnout milestones as defined in the share exchange agreement with Health Sciences Acquisitions Corporation. As a result, all of the 20,000,000 earnout shares of Immunovant, Inc.’s common stock were issued, including 17,547,938 shares of common stock issued to RSL.

In April 2020, Immunovant, Inc. completed an underwritten public offering of 9,613,365 shares of its common stock, including 1,034,483 shares of common stock purchased by RSL, at a price of \$14.50 per share for net proceeds to Immunovant, Inc. of approximately \$131.0 million, after deducting underwriting discounts and commissions and offering expenses. The proceeds included \$15.0 million received from RSL.

In May 2020, Immunovant, Inc.’s 11,500,000 outstanding warrants became exercisable for an aggregate of 5,750,000 shares of Immunovant, Inc.’s common stock at a price of \$11.50 per share. An aggregate of 11,438,290 outstanding warrants were exercised for an aggregate of 5,719,145 shares of Immunovant, Inc.’s common stock at a price of \$11.50 per share, for net proceeds of approximately \$65.8 million. The remaining 61,710 warrants were cancelled.

In September 2020, Immunovant, Inc. completed an underwritten public offering of 6,060,606 shares of its common stock, including 380,000 shares of common stock purchased by RSL, at a price of \$33.00 per share for net proceeds to Immunovant, Inc. of approximately \$188.1 million, after deducting underwriting discounts and commissions and offering expenses. The proceeds included \$12.5 million received from RSL.

### ***Proteovant***

In July 2021, Proteovant collected the subscription receivable relating to the second \$100.0 million payment due under a subscription agreement entered into with SK, Inc. (“SK”) in December 2020 pursuant to which SK agreed to make a \$200.0 million equity investment in Proteovant, representing an ownership interest of 40.0% on the closing date.

## **Note 10—Share-Based Compensation**

### **(A) Share-Based Compensation Expense**

Share-based compensation expense was as follows (in thousands):

	<b>Years Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Share-based compensation expense recognized as:		
R&D expenses	\$ 63,735	\$ 22,637
G&A expenses	501,221	62,321
Total	<u>\$564,956</u>	<u>\$ 84,958</u>

The achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination resulted in the recognition of a one-time catch-up expense of \$372.9 million in September 2021 relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. This one-time catch-up expense is reflected in the accompanying consolidated statements of operations for the year ended March 31, 2022.

## (B) RSL Equity Incentive Plans

RSL has three equity incentives plans: the Roivant Sciences Ltd. 2021 Equity Incentive Plan (the “RSL 2021 EIP”), the Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan (the “RSL 2015 EIP”), and the Roivant Sciences Ltd. Amended and Restated 2015 Restricted Stock Unit Plan (the “2015R Plan”) (collectively, the “RSL Equity Plans”). The RSL 2021 EIP was approved and adopted in connection with the Business Combination and became effective immediately prior to closing. Since the effective date of the RSL 2021 EIP, no further stock awards have been or will be made under the RSL 2015 EIP. Additionally, no further stock awards will be made under the 2015R Plan. As of March 31, 2022, 69,300,000 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 our board of directors in its discretion. 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, restricted stock units and other stock awards under the RSL 2021 EIP. At March 31, 2022, a total of 59,373,756 common shares were available for future grants under the RSL 2021 EIP.

All RSL common shares issuable on exercise of vested options or settlement of other equity instruments that were issued and outstanding as of the closing of the Business Combination were subject to a six-month lock-up period. The lock-up period expired on March 30, 2022.

### *Stock Options and Performance Stock Options*

Activity for stock options and performance stock options under the RSL Equity Plans for the year ended March 31, 2022 is 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, 2021	69,687,308	\$ 11.64	5.89	
Granted	12,181,127	\$ 9.76		
Exercised	(101,436)	\$ 4.06		
Forfeited/Canceled	(1,402,095)	\$ 11.86		
Options outstanding at March 31, 2022	<u>80,364,904</u>	\$ 11.37	5.50	\$ 1,899
Options exercisable at March 31, 2022	<u>39,236,351</u>	\$ 11.15	4.70	\$ 1,456

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, 2022. At March 31, 2022, total unrecognized compensation expense related to non-vested stock options and performance stock options was approximately \$149.7 million and is expected to be recognized over a weighted-average period of approximately 2.63 years.

At March 31, 2022 and 2021, there were 39,236,351 and 16,193,146 vested stock options and performance stock options, respectively. Vesting for performance stock options was subject to a liquidity event vesting requirement in addition to time-based service requirements. The liquidity event vesting requirement was met upon closing of the Business Combination on September 30, 2021.

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, 2022 and 2021.

Assumptions	Years Ended March 31,	
	2022	2021
Expected stock price volatility	81.70%	74.84%
Expected risk free interest rate	1.13%	0.43%
Expected term, in years	6.25	6.25
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,	
	2022	2021
Intrinsic value of options exercised	\$ 89	\$ —
Grant date fair value of options vested	\$210,487	\$25,711
Weighted-average grant date fair value per share of stock options granted	\$ 6.85	\$ 8.67

### ***Restricted Stock Units and Performance Stock Units***

Activity for restricted stock units and performance stock units under the RSL Equity Plans for the year ended March 31, 2022 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested balance at March 31, 2021	7,294,028	\$ 11.86
Granted	20,948,227	\$ 10.44
Vested	(5,111,550)	\$ 11.60
Forfeited	(1,173,956)	\$ 10.79
Non-vested balance at March 31, 2022	21,956,749	\$ 10.63

The total fair value of restricted stock units and performance stock units vested during the year ended March 31, 2022 was \$59.3 million. Vesting for both restricted stock units and performance stocks units was subject to a liquidity event vesting requirement. There were no vested restricted stock units or performance stock units at March 31, 2021 as the liquidity event vesting requirement was not met until the closing of the Business Combination on September 30, 2021. Restricted stock units vest upon the achievement of time-based service requirements. The vesting of performance stock units requires that certain performance conditions are achieved during the performance period and is subject to continued service requirements.

At March 31, 2022, total unrecognized compensation expense related to non-vested restricted stock units and performance stock units was approximately \$155.8 million. Unrecognized compensation expense relating to restricted stock units and performance stock units that are deemed probable of vesting is expected to be recognized over a weighted-average period of approximately 2.97 years.

## ***Capped Value Appreciation Rights***

### ***March 2020 CVAR Grants***

In March 2020, the Company granted capped value appreciation rights (“CVARs”) that will pay at settlement the excess in shares of (a) the lesser of (i) the fair market value of a common share as of the settlement date or (ii) the cap of \$12.68, over (b) the hurdle price of either \$6.40 or \$11.50, as applicable to each grant. On March 30, 2022, the Company amended the outstanding CVARs that were granted in March 2020. Pursuant to the amendment, in the event any CVARs have satisfied the time-based service and liquidity event vesting requirements (“service-vested CVARs”) but have not satisfied the applicable hurdle price on an applicable measurement date, then such CVARs will be deemed to remain outstanding and the applicable award holder will be provided the right to earn such CVARs if the hurdle price is satisfied on subsequent annual “hurdle measurement dates” prior to the original expiration date of the CVARs, being March 31, 2026. The “hurdle measurement dates” are March 30 of each of years 2023 through 2026. If the hurdle price is not satisfied on any such subsequent annual hurdle measurement date prior to the expiration date of the CVARs, then the CVARs will be forfeited in their entirety on the expiration date. This amendment was accounted for as a modification and resulted in an aggregate of approximately \$16.9 million of incremental fair value. Incremental fair value associated with CVARs that do not require further service for vesting was recognized in full on March 30, 2022. The Company will recognize the incremental fair value for CVARs that require future service for vesting over the remaining requisite service period.

Activity for CVARs under the RSL 2015 EIP for the year ended March 31, 2022 is as follows:

	<b>Number of CVARs</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-service-vested CVARs balance at March 31, 2021	32,447,626	\$ 0.72
Granted	—	\$ —
Service-vested	(18,213,910)	\$ 1.22
Forfeited	(435,630)	\$ 0.40
Non-service-vested CVARs balance at March 31, 2022	<u>13,798,086</u>	\$ 1.25

At March 31, 2022, there were 18,213,910 service-vested CVARs. The hurdle price was not satisfied for these service-vested CVARs and as such they remain outstanding. The total fair value of CVARs that service-vested during the year ended March 31, 2022 was \$22.3 million. There were no service-vested CVARs at March 31, 2021 as the liquidity event vesting requirement was not met until the closing of the Business Combination on September 30, 2021.

At March 31, 2022, total unrecognized compensation expense related to non-service-vested CVARs was approximately \$10.1 million and is expected to be recognized over a weighted-average period of approximately 1.74 years.

### ***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, 2022 is as follows:

	<u>Number of CVARs</u>	<u>Weighted Average Grant Date Fair Value</u>
Non-vested balance at March 31, 2021	—	\$ —
Granted	6,317,350	\$ 4.95
Forfeited	<u>(32,100)</u>	<u>\$ 4.71</u>
Non-vested balance at March 31, 2022	<u>6,285,250</u>	<u>\$ 4.95</u>

At March 31, 2022, total unrecognized compensation expense related to non-vested CVARs was approximately \$19.3 million and is expected to be recognized over a weighted-average period of approximately 3.13 years.

### (C) Employee Stock Purchase Plan

In September 2021, the Company adopted the Roivant Sciences Ltd. Employee Stock Purchase Plan (the “RSL ESPP”), which provides for the granting of an option to purchase common shares of RSL to eligible employees, as defined by the RSL ESPP. As of March 31, 2022, the maximum number of common shares reserved and available for purchase under the RSL ESPP was 13,900,000. The total number of common shares available for purchase under the RSL ESPP will be increased annually on April 1 of each year during the term of the plan in an amount equal to the least of (i) 13,900,000 common shares, (ii) one percent of the aggregate number of common shares outstanding (on a fully diluted basis) on the last day of the immediately preceding Company fiscal year and (iii) such lesser number of common shares as determined by the board of directors; provided that the maximum number of common shares that may be issued under the RSL ESPP during the term of the plan is 147,447,650 common shares.

### (D) Subsidiary Equity Incentive Plans

Certain wholly owned and majority-owned or controlled subsidiaries of RSL adopt their own equity incentive plan (“EIP”). Each EIP is generally structured so that the applicable subsidiary, and its affiliates’ employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted stock unit awards, and other share awards under their respective EIP. The Company recorded share-based compensation expense of \$47.4 million and \$29.1 million for the years ended March 31, 2022 and 2021, respectively, related to subsidiary EIPs. At March 31, 2022, total unrecognized compensation expense related to subsidiary EIPs was approximately \$134.5 million.

### Note 11—Income Taxes

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

	<u>Years Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Loss before income taxes:		
Bermuda <sup>(1)</sup>	\$ 390,831	\$(227,471)
United States	(747,953)	(212,921)
Switzerland	(544,870)	(424,494)
Other <sup>(2)</sup>	<u>(21,755)</u>	<u>(33,661)</u>
Total loss before income taxes	<u>\$(923,747)</u>	<u>\$(898,547)</u>

(1) Primarily entities which are centrally managed and controlled in the United Kingdom

(2) Primarily Greater China and United Kingdom activity



	Years Ended March 31,	
	2022	2021
<b>Current taxes:</b>		
Bermuda	\$ —	\$ —
United States	(223)	1,365
Switzerland	—	—
Other <sup>(1)</sup>	592	321
Total current tax expense	\$ 369	\$ 1,686
<b>Deferred taxes:</b>		
Bermuda	\$ —	\$ —
United States	—	—
Switzerland	—	—
Other	—	—
Total deferred tax benefit	\$ —	\$ —
Total income tax expense	\$ 369	\$ 1,686

(1) Primarily Greater China and United Kingdom activity

A reconciliation of income tax provision/(benefit) computed at the Bermuda statutory rate to income tax expense reflected in the consolidated financial statements is as follows (in thousands, except percentages):

	Year Ended March 31, 2022		Year Ended March 31, 2021	
	\$	%	\$	%
Income tax benefit at Bermuda statutory rate	\$ —	— %	\$ —	— %
Foreign rate differential <sup>(1)</sup>	(179,000)	19.38%	(150,778)	16.78%
Permanent disallowed IPR&D	15,347	(1.66)%	111,432	(12.40)%
Tax-effect of changes in the fair value of investments and loss from equity method investment	15,169	(1.64)%	(22,472)	2.50%
Nontaxable gain on sale of investment	(84,313)	9.13%	—	— %
Nontaxable gain on deconsolidation of business	(958)	0.10%	(16,438)	1.83%
Nondeductible executive compensation	25,973	(2.81)%	905	(0.10)%
Tax deficiencies (excess tax benefits) from share-based compensation	12,918	(1.40)%	(439)	0.05%
Other permanent adjustments	10,912	(1.18)%	2,457	(0.28)%
Research tax credits	(10,113)	1.09%	(10,555)	1.17%
Valuation allowance	205,811	(22.28)%	85,046	(9.46)%
Tax rate changes	(2,444)	0.26%	2,443	(0.27)%
Other	(8,933)	0.97%	85	(0.01)%
Total income tax expense	\$ 369	(0.04)%	\$ 1,686	(0.19)%

(1) Primarily related to operations in the United States, Switzerland, the United Kingdom, and other jurisdictions with statutory tax rates different than the Bermuda rate.

The Company's effective tax rates for the years ended March 31, 2022 and 2021 was (0.04)% and (0.19)%, respectively, driven by the Company's jurisdictional earnings by location 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, 2022 and 2021 are as follows (in thousands):

	March 31, 2022	March 31, 2021
<b>Deferred tax assets</b>		
Research tax credits	\$ 27,155	\$ 19,063
Intangible assets	61,544	50,564
Net operating loss	312,749	202,906
Share-based compensation	93,177	26,623
Lease liabilities	15,406	16,638
Other assets	20,651	7,303
Subtotal	530,682	323,097
Valuation allowance	(512,736)	(303,287)
<b>Deferred tax liabilities</b>		
Depreciation	(1,397)	(1,214)
Right-of-use assets	(12,661)	(13,908)
Other liabilities	(3,888)	(4,688)
Total deferred tax assets/(liabilities)	<u>\$ —</u>	<u>\$ —</u>

The Company has Federal net operating losses in Switzerland, the United States, the United Kingdom and other jurisdictions in the amount of \$1,749.2 million, \$244.1 million, \$40.1 million, and \$98.4 million, respectively. The Switzerland net operating losses will expire in varying amounts between March 31, 2025 and March 31, 2029. The United States 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 United Kingdom and other net operating losses can be carried forward indefinitely as well, with an annual limitation on utilization. The Company has generated net operating losses from United States state and local jurisdictions in the amount of \$94.8 million which will expire in varying amounts between March 31, 2035 and March 31, 2042. The Company has generated \$27.2 million of research tax credit carryforwards primarily in the United States and Canada, which will expire in varying amounts between March 31, 2035 and March 31, 2042.

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 which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of \$512.7 million as of March 31, 2022, representing the portion of the deferred tax asset that is not more likely than not to be realized. For the period April 1, 2021 through March 31, 2022, the valuation allowance increased by \$209.4 million, primarily as a result of corresponding increases in our global net operating losses, as well as increased costs related to share-based compensation. 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 United Kingdom 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 United States, United Kingdom, 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, 2018 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 year ended March 31, 2022 was not material to the Company's consolidated financial statements. There were no unrecognized tax benefits recorded as of March 31, 2021. No interest and penalties related to unrecognized tax benefits were recorded as of March 31, 2022 or March 31, 2021.

#### Note 12—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.

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

	<u>Years Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Operating lease cost	\$ 13,649	\$ 11,931
Short-term lease cost	326	237
Variable lease cost	1,227	704
Total operating lease cost	<u>\$ 15,202</u>	<u>\$ 12,872</u>

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

	<u>During the Year Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Cash paid for operating lease liabilities	\$ 14,403	\$ 8,830
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$ 6,035	\$ 5,491

	<u>March 31, 2022</u>	<u>March 31, 2021</u>
Weighted average remaining lease term (in years)	9.0	9.6
Weighted average discount rate	7.0%	7.1%

As of March 31, 2022, maturities of operating lease liabilities were as follows (in thousands):

<u>Years Ending March 31,</u>	
2023	\$ 12,714
2024	12,672
2025	10,455
2026	9,363
2027	8,680
Thereafter	46,783
Total lease payments	<u>100,667</u>
Less: present value adjustment	(24,996)
Less: tenant improvement allowance	(1,805)
Total	<u>\$ 73,866</u>

## **Note 13—Commitments and Contingencies**

### **(A) Commitments**

#### ***Long-Term Debt***

The Company is obligated to make contractual payments related to its long-term debt. Refer to Note 7, “Long-Term Debt and Loan Commitment” for further information.

#### ***Lease Commitments***

The Company has operating leases, consisting primarily of real estate leases. Refer to Note 12, “Leases” for further information.

#### ***Other Commitments***

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

In November 2021, the Company’s subsidiary, Immunovant, Inc. (“Immunovant”), entered into a Product Service Agreement with Samsung Biologics Co., Ltd. (“Samsung”) by which Samsung will manufacture and supply Immunovant with batoclimab drug substance for commercial sale and perform other manufacturing-related services with respect to batoclimab. As of March 31, 2022, the minimum purchase commitment related to this agreement is estimated to be approximately \$36.0 million.

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

### **(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. The Company is currently not involved in any legal proceedings with a probable and estimable material loss.

#### ***Immunovant***

As the Company’s subsidiary, Immunovant, has previously disclosed, in February 2021, a putative securities class action complaint was filed against Immunovant and certain of its current and former officers in the U.S. District Court for the Eastern District of New York on behalf of a class consisting of those who acquired Immunovant’s securities from October 2, 2019 and February 1, 2021. The complaint alleged that Immunovant and certain of its officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and misleading statements regarding the safety of batoclimab and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys’ fees.

On December 29, 2021, the U.S. District Court appointed a lead plaintiff. On February 1, 2022, the lead plaintiff filed an amended complaint adding both (i) the Company and (ii) Immunovant's directors and underwriters as defendants, and asserting additional claims under Section 11, 12(a)(2), and 15 of the Securities Act of 1933, which was further amended by an amended complaint filed on March 15, 2022. On May 27, 2022, defendants, including the Company, filed motions to dismiss that amended complaint. The Company intends to vigorously defend the case and has not recorded a liability related to this lawsuit because, at this time, the Company is unable to reasonably estimate possible losses or determine whether an unfavorable outcome is either probable or remote.

In March 2022, Acuitas Therapeutics Inc. filed a lawsuit in the U.S. District Court for the Southern District of New York against two of the Company's affiliates, Genevant and Arbutus, seeking a declaratory judgment that U.S. Patents 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127, 9,504,651, 9,518,272, and 11,141,378 are not infringed by the manufacture, use, offer for sale, sale or importation into the United States of COMIRNATY, Pfizer's and BioNTech's vaccine for COVID-19 and are otherwise invalid. Each of Genevant and Arbutus intend to vigorously defend the case and neither they nor the Company have recorded a liability related to this lawsuit.

### **(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 maintain director and officer liability insurance, which may cover certain liabilities arising from our obligation to indemnify our directors. The Company has not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. To date, the Company has not incurred any material costs and have not accrued any liabilities related to such obligations in the consolidated financial statements as of March 31, 2022 and 2021.

## 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, 2022 and 2021, by level, within the fair value hierarchy (in thousands):

	As of March 31, 2022				As of March 31, 2021			
	Level 1	Level 2	Level 3	Balance as of March 31, 2022	Level 1	Level 2	Level 3	Balance as of March 31, 2021
<b>Assets:</b>								
Money market funds	\$ 1,297,844	\$ —	\$ —	\$ 1,297,844	\$ 1,420,597	\$ —	\$ —	\$ 1,420,597
Investment in Datavant Class A units	—	—	193,963	193,963	—	—	—	—
Investment in Sio common shares	12,447	—	—	12,447	48,487	—	—	48,487
Investment in Arbutus common shares	115,765	—	—	115,765	53,325	—	—	53,325
Investment in Arbutus convertible preferred shares	—	—	—	—	—	76,037	—	76,037
Other investments	3,659	—	—	3,659	11,129	—	—	11,129
Total assets at fair value	<u>\$ 1,429,715</u>	<u>\$ —</u>	<u>\$ 193,963</u>	<u>\$ 1,623,678</u>	<u>\$ 1,533,538</u>	<u>\$ 76,037</u>	<u>\$ —</u>	<u>\$ 1,609,575</u>
<b>Liabilities:</b>								
Debt issued by Dermavant to NovaQuest	\$ —	\$ —	\$ 177,400	\$ 177,400	\$ —	\$ —	\$ 150,100	\$ 150,100
Liability instruments measured at fair value <sup>(1)</sup>	18,019	—	26,893	44,912	—	—	67,893	67,893
Total liabilities at fair value	<u>\$ 18,019</u>	<u>\$ —</u>	<u>\$ 204,293</u>	<u>\$ 222,312</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 217,993</u>	<u>\$ 217,993</u>

<sup>(1)</sup> At March 31, 2022, Level 1 includes the fair value of the Public Warrants of \$18.0 million, and Level 3 includes the fair value of the Earn-Out Shares of \$9.2 million, Private Placement Warrants of \$9.1 million, and other liability instruments issued of \$8.6 million. At March 31, 2021, Level 3 includes the fair value of the Sumitomo Options of \$62.4 million and other liability instrument issued of \$5.5 million.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the years ended March 31, 2022 and 2021.

### Level 3 Disclosures

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

The fair value of Level 3 assets and liabilities may change significantly as additional data are obtained, impacting the Company's assumptions regarding probabilities of potential scenarios used to estimate fair value. In evaluating this information, considerable judgment is required to interpret the data used to develop the

assumptions and estimates. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The changes in fair value of the Level 3 assets during the year ended March 31, 2022 were as follows (in thousands):

Balance at March 31, 2021	\$ —
Fair value of investment in Datavant at recognition date	224,147
Changes in fair value of investment in Datavant, included in net loss	(30,184)
Balance at March 31, 2022	<u>\$ 193,963</u>

There were no Level 3 assets held during the year ended March 31, 2021.

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

Balance at March 31, 2020	\$ 191,473
Changes in fair value of debt and liability instruments, included in net loss	29,845
Liability instruments disposed due to deconsolidation of subsidiary	(3,325)
Balance at March 31, 2021	<u>217,993</u>
Fair value of liability instrument issued	38,634
Changes in fair value of debt and liability instruments, included in net loss	9,226
Settlements	(88)
Termination of DSP Options	(61,472)
Balance at March 31, 2022	<u>\$ 204,293</u>

### Investment in Datavant

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

<u>Input</u>	<u>Point Estimate Used</u> <u>As of March 31, 2022</u>
Volatility	110.0%
Risk-free rate	1.62%

### Debt issued by Dermavant to NovaQuest

The fair value of the debt instrument as of March 31, 2022 and 2021 represents the fair value of amounts payable to NovaQuest using the Monte Carlo simulation method under the income approach determined by using probability assessments of the expected future payments through 2032 and applying discount rates ranging from 10% to 12%. The future payments are based on significant inputs that are not observable in the market which are subject to remeasurement at each reporting date. The estimates of fair value may not be indicative of the amounts that could ultimately be paid by Dermavant to NovaQuest.

## Earn-Out Shares

The fair value of the Earn-Out Shares issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to include the lock-up periods to which the Earn-Out Shares are subject. Refer to Note 3, “Business Combination with MAAC” for additional details. Significant unobservable inputs used to calculate the fair value of the Earn-Out Shares included the following:

<u>Input</u>	<u>Point Estimate Used</u> <u>As of March 31, 2022</u>
Volatility	82.3%
Risk-free rate	2.43%

As of March 31, 2022, the fair value of the Earn-Out Shares was \$9.2 million. Earn-Out Shares are included in “Liability instruments measured at fair value” in the accompanying consolidated balance sheets.

## Private Placement Warrants

The fair value of the Private Placement Warrants issued as part of the Business Combination was calculated using the Monte Carlo simulation method under the income approach. The model was structured to incorporate the redemption features as discussed in Note 3, “Business Combination with MAAC” and the added restriction by which the Company cannot redeem the Private Warrants if the Reference Value is greater than \$18.00. Significant unobservable inputs used to calculate the fair value of the Private Placement Warrants included the following:

<u>Input</u>	<u>Point Estimate Used</u> <u>As of March 31, 2022</u>
Volatility	56.5%
Risk-free rate	2.43%
Term (in years)	4.50

As of March 31, 2022, the fair value of the Private Placement Warrants was \$9.1 million. The Private Placement Warrants are included in “Liability instruments measured at fair value” in the accompanying consolidated balance sheets.

## Sumitomo Options

Prior to termination in June 2021, the fair value of the options to acquire the Company’s interest in certain of its subsidiaries, which were granted to Sumitomo under the Sumitomo Transaction Agreement, was calculated using significant unobservable inputs including the following:

<u>Input</u>	<u>Range or Point</u> <u>Estimate Used</u> <u>As of March 31, 2021</u>
Time to expiration (in years)	3.59
Risk-free rate	0.52%
Volatility	89.0% - 95.0%

In June 2021, the Company completed a transaction with Sumitomo pursuant to which Sumitomo terminated all of its existing options to acquire the Company’s equity interests in certain subsidiaries. As of March 31, 2021, the fair value of the Sumitomo Options was \$62.4 million, which is included in “Liability instruments measured at fair value” in the accompanying consolidated balance sheets. See Note 8, “Related Party Transactions” for additional information.



**Note 15—Other Expense, Net**

Other expense, net was as follows (in thousands):

	<b>Years Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Loss from equity method investment	\$ —	\$ 3,750
Interest income	(369)	(1,418)
Interest expense	7,041	2,809
Other (income) expense	(3,237)	3,560
<b>Total</b>	<b>\$ 3,435</b>	<b>\$ 8,701</b>

**Note 16—Net Loss per Common Share**

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

For periods of loss, diluted loss per share is calculated similar to basic loss per share as the effect of including all potentially dilutive common stock equivalents is anti-dilutive. All outstanding common stock equivalents have been excluded from the computation of diluted loss per share because their effect was anti-dilutive due to the net loss.

As of March 31, 2022 and 2021, potentially dilutive securities were as follows:

	<b>March 31, 2022</b>	<b>March 31, 2021</b>
Stock options and performance stock options	80,364,904	69,687,308
Restricted stock units and performance stock units (non-vested)	21,956,749	7,294,028
March 2020 CVARs <sup>(1)</sup>	32,011,996	32,447,626
November 2021 CVARs	6,285,250	—
Restricted common stock (non-vested)	741,405	1,720,090
Earn-Out Shares (non-vested)	3,080,387	—
Private Placement Warrants	10,214,365	—
Public Warrants	20,475,875	—
Other instruments issued	5,103,577	5,458,543

<sup>(1)</sup> Refer to Note 10, “Share-Based Compensation” for details regarding settlement of CVARs.

**Note 17—Subsequent Events**

In May 2022, VTAMA (tapinarof) cream was approved by the FDA as the first and only FDA-approved steroid-free topical medication in its class for the treatment of plaque psoriasis in adult patients.

Following the approval of VTAMA cream by the FDA in May 2022, Dermavant received \$160.0 million in June 2022 pursuant to the terms of the RIPSAs as described in Note 7, “Long-Term Debt and Loan Commitment.”

Also, as a result of FDA approval, Dermavant achieved a regulatory milestone to GSK of £100.0 million (approximately \$126 million on the date of achievement), which will be paid within 70 calendar days of FDA approval. Additionally, the first sale of VTAMA cream in May 2022 resulted in the achievement of a milestone to Welicem Biotech Inc. of CAD\$25.0 million (approximately \$20 million on the date of achievement), which will be paid within 60 calendar days of the invoice date. Dermavant intends to primarily use the RIPSAs proceeds for the payment of these obligations.

**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**

Our management, with the participation of our Principal Executive Officer, our Principal Financial Officer and our Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022 and concluded that our disclosure controls and procedures were effective as of that date. The term “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”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive, principal financial and principal accounting officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Management’s Annual Report on Internal Control over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

**ITEM 9B. OTHER INFORMATION**

None.

**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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2022.

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](http://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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2022.

### **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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2022.

### **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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2022.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended March 31, 2022.

## 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 I, 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.

### ITEM 16. FORM 10-K SUMMARY

None.

#### 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.	—	—	—	Filed herewith
2.2#*	Agreement and Plan of Merger, dated as of February 2, 2021, by and among Roivant Sciences Ltd., Silicon Insite, Inc., Silicon TX China, Silicon Therapeutics, LLC and Silicon SWAT, Inc.	S-4/A	333-256165	2.2	July 1, 2021
2.3#*	Stock Purchase Agreement, dated as of November 6, 2020, by and among Oncopia Therapeutics, Inc., Pharmavant 5, Inc., certain selling securityholders and certain seller representatives	S-4/A	333-256165	2.3	July 1, 2021
2.4#*	Amendment No. 1 to the Stock Purchase Agreement, dated as of November 17, 2020, by and among Oncopia Therapeutics, Inc., Pharmavant 5, Inc., certain selling securityholders and WRYP Stockholders Services, LLC	S-4/A	333-256165	2.4	July 1, 2021

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
2.5*	Transaction Agreement, dated as of October 31, 2019, by and among Sumitomo Dainippon Pharma Co., Ltd., Vant Alliance Ltd., Roivant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd. and Spiroivant Sciences Ltd.	SC 13D/A	—	7.04	November 4, 2019
2.6#*	Asset Purchase Agreement, dated as of July 10, 2018, by and among GlaxoSmithKline Intellectual Property Development Ltd., Glaxo Group Limited and Dermavant Sciences GmbH	S-4	333-256165	2.6	May 14, 2021
2.7#*	Asset Purchase Agreement, dated as of May 29, 2012, by and between Glaxo Group Limited and Welichem Biotech Inc.	S-4	333-256165	2.7	May 14, 2021
2.8#*	First Amendment to the Asset Purchase Agreement, dated as of August 31, 2012, by and between Glaxo Group Limited and Welichem Biotech, Inc.	S-4	333-256165	2.8	May 14, 2021
2.9+	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.	—	—	—	Filed herewith
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*	Warrant Agreement between Continental Stock Transfer & Trust Company and Montes Archimedes Acquisition Corp.	8-K	001-39597	4.1	October 13, 2020
4.2*	Specimen Ordinary Share Certificate of Roivant Sciences Ltd.	S-4/A	333-256165	4.5	August 3, 2021
4.3*	Specimen Warrant Certificate of Roivant Sciences Ltd.	S-4/A	333-256165	4.6	August 3, 2021
4.4*	Form of Warrant Assumption Agreement, by and between Montes Archimedes Acquisition Corp., Roivant Sciences Ltd. and American Stock Transfer & Trust Company, LLC	S-4/A	333-256165	4.7	August 3, 2021

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
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	—	—	—	Filed herewith
10.2+	Form of Subscription Agreement	—	—	—	Filed herewith
10.3+	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.	—	—	—	Filed herewith
10.4+	Form of Transaction Support Agreement, dated as of May 1, 2021, by and among Roivant Sciences Ltd., Montes Archimedes Acquisition Corp. and certain shareholders of Roivant Sciences Ltd.	—	—	—	Filed herewith
10.5*	Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and Montes Archimedes Acquisition Corp.	8-K	001-39597	10.1	October 13, 2020
10.6#*	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
10.7#*	Collaboration and License Agreement, dated as of January 15, 2020, by and between Dermavant Sciences GmbH and Japan Tobacco Inc.	S-4	333-256165	10.7	May 14, 2021
10.8#*	Clinical Manufacturing and Supply Agreement, dated August 20, 2018, by and between Dermavant Sciences GmbH and GlaxoSmithKline Trading Services Limited	S-4	333-256165	10.8	May 14, 2021
10.9#*	Commercial Manufacturing and Supply Agreement, dated April 1, 2019, by and between Dermavant Sciences GmbH and GlaxoSmithKline Trading Services Limited	S-4	333-256165	10.9	May 14, 2021

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.10#*	Funding Agreement, dated as of July 10, 2018, by and between Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P.	S-4	333-256165	10.10	May 14, 2021
10.11#*	First Amendment to Funding Agreement, dated as of October 11, 2018, by and between Dermavant Sciences GmbH and NovaQuest Co-Investment Fund VIII, L.P.	S-4	333-256165	10.11	May 14, 2021
10.12#*	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
10.13#*	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
10.14#*	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
10.15#*	Research Agreement, dated as of January 1, 2018, by and between Oncopia Therapeutics, LLC and the Regents of the University of Michigan	S-4/A	333-256165	10.20	July 1, 2021
10.16#*	Fifth Amendment to the Sponsored Research Agreement, dated as of November 19, 2020, by and between Oncopia Therapeutics, Inc. and the Regents of the University of Michigan	S-4/A	333-256165	10.21	July 1, 2021
10.17#*	Amended and Restated Patent License Agreement, dated as of November 16, 2020, by and between Oncopia Therapeutics, Inc. and the Regents of the University of Michigan	S-4/A	333-256165	10.22	July 1, 2021
10.18#*	Investors' Rights Agreement, dated as of January 11, 2021, by and among Pharmavant 5, Inc., Roivant Sciences Ltd. and SK Holdings Co., Ltd.	S-4/A	333-256165	10.23	July 1, 2021

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.19*	Form of Indemnity Agreement	S-4/A	333-256165	10.24	July 1, 2021
10.20*^	Roivant Sciences Ltd. Amended and Restated 2015 Equity Incentive Plan	S-4	333-256165	10.25	May 14, 2021
10.21*^	Roivant Sciences Ltd. 2021 Equity Incentive Plan	S-8	333-260173	99.1	October 8, 2021
10.22*^	Amended and Restated Employment Agreement between Roivant Sciences, Inc. and Vivek Ramaswamy, dated as of May 14, 2021	S-4	333-256165	10.27	May 14, 2021
10.23*^	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
10.24*^	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
10.25*^	Executive Employment Agreement between Roivant Sciences, Inc. and Benjamin Zimmer, dated as of May 14, 2021	S-4	333-256165	10.30	May 14, 2021
10.26#*	Credit Agreement by and among Dermavant Sciences Ltd., Dermavant Holdings Limited, Dermavant Sciences IRL Limited, Dermavant Sciences GmbH, certain subsidiaries of Dermavant Sciences Ltd., XYQ Luxco S.A.R.L. and U.S. Bank National Association, as collateral agent, dated as of May 14, 2021	S-4/A	333-256165	10.31	July 1, 2021
10.27#*	Revenue Interest Purchase and Sale Agreement by and among Dermavant Sciences GmbH, certain purchasers and U.S. Bank National Association as collateral agent, dated as of May 14, 2021	S-4/A	333-256165	10.32	July 1, 2021
10.28+	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.	—	—	—	Filed herewith



Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
10.29*	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
10.30*^	Roivant Sciences Ltd. Employee Stock Purchase Plan	S-8	333-260173	99.2	October 8, 2021
10.31#†*	Agreement and General Release Between Roivant Sciences Ltd., Roivant Sciences, Inc. and Benjamin Zimmer	10-Q	001-40782	10.1	November 15, 2021
10.32#*	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
10.33*	Bonus Award Letter from Roivant Sciences Inc. to Benjamin Zimmer, dated as of December 21, 2021	S-1	333-261853	10.38	December 22, 2021
10.34#†*	Exclusive License Agreement, dated as of November 24, 2021, by and between Eisai Co. Ltd and Pharmavant 7 GmbH	10-Q	001-40782	10.1	February 14, 2022
10.35#*	Common Shares Purchase Agreement, dated as of February 14, 2022, by and between Roivant Sciences Ltd. and CF Principal Investments LLC	8-K	001-40782	10.1	February 14, 2022
10.36#†	Investor Rights Agreement, dated as of September 13, 2021, by and among Priovant Holdings, Inc., Roivant Sciences Ltd. and Pfizer Inc.	—	—	—	Filed herewith
10.37#†	License and Collaboration Agreement, dated as of September 13, 2021, by and between Pfizer Inc. and Priovant, Inc.	—	—	—	Filed herewith
10.38#	Amendment No. 1 to License and Collaboration Agreement, dated as of June 10, 2022, by and between Pfizer Inc. and Priovant, Inc.	—	—	—	Filed herewith
21.1	List of Subsidiaries of Roivant Sciences Ltd.	—	—	—	Filed herewith

Exhibit Number	Description	Incorporated by Reference			Filing Date
		Form	File No.	Exhibit	
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
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.
- + This exhibit was previously filed with the Company's Form S-4 (File No. 333-256165). For administrative convenience, the Company has re-filed this exhibit with this Form 10-K.
- † 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).

## 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: June 28, 2022

By: /s/ Matt Maisak

Name: Matt Maisak

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 Matt Maisak, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Matthew Gline</u> Matthew Gline	Chief Executive Officer and Director (Principal Executive Officer)	June 28, 2022
<u>/s/ Richard Pulik</u> Richard Pulik	Chief Financial Officer (Principal Financial Officer)	June 28, 2022
<u>/s/ Rakhi Kumar</u> Rakhi Kumar	Chief Accounting Officer (Principal Accounting Officer)	June 28, 2022
<u>/s/ Vivek Ramaswamy</u> Vivek Ramaswamy	Director	June 28, 2022
<u>/s/ Andrew Lo</u> Andrew Lo	Director	June 28, 2022
<u>/s/ Keith Manchester</u> Keith Manchester	Director	June 28, 2022
<u>/s/ Ilan Oren</u> Ilan Oren	Director	June 28, 2022

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Daniel Gold</u> Daniel Gold	Director	June 28, 2022
<u>/s/ Masayo Tada</u> Masayo Tada	Director	June 28, 2022
<u>/s/ Patrick Machado</u> Patrick Machado	Director	June 28, 2022
<u>/s/ James C. Momtazee</u> James C. Momtazee	Director	June 28, 2022