

## Risk Factors Comparison 2024-05-30 to 2023-06-28 Form: 10-K

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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~~ **common Shares** ~~shares~~ could decline, and you could lose all or part of your investment. Unless the context otherwise requires, references in this section to “we,” “us,” “our,” “Roivant” and the “Company” refer to Roivant Sciences Ltd. and its subsidiaries and affiliates, as the context requires. Risks Related to Our Business and Industry Risks Related to Our Financial Position and Strategy Our limited operating history and the inherent uncertainties and risks involved in biopharmaceutical product development **and commercialization** 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~~ **limited** revenue from our operations since inception, and there is no guarantee that we will ~~do so~~ **generate significant revenues** in the future. We are a commercial-stage biopharmaceutical and healthcare technology company with a limited operating history upon which you can evaluate our business and prospects. We were formed in April 2014, and our operations to date have primarily been limited to acquiring or in-licensing product candidates, pursuing the clinical development and commercialization of those product candidates, efforts to discover new product candidates, financing activities and the creation or acquisition of healthcare technology companies and products, as well as the oversight and management of our subsidiaries developing and commercializing medicines, which we refer to as “Vants.” ~~Last year, following~~ **Following** the approval by the U. S. Food and Drug Administration (the “FDA”) in May 2022 of VTAMA® (tapinarof) **cream, 1 %**, for the treatment of adults with plaque psoriasis, we commenced our transition from a clinical-stage ~~to a company to one~~ with commercial-stage assets. **In February 2024, we submitted a Supplemental New Drug Application (“sNDA”) to the FDA for VTAMA for the topical treatment of atopic dermatitis (“AD”) in adults and children 2 years of age and older.** VTAMA is not currently approved in any other jurisdictions and we do not have any other product candidates that have received regulatory approvals in the U. S. or in any other jurisdiction. Our ability to execute on our business model and generate revenues depends on a number of factors, including our ability to: • successfully continue to commercialize VTAMA; ~~• identify new acquisition or in-licensing opportunities;~~ • successfully complete ongoing preclinical studies and clinical trials and obtain regulatory approvals for our current and future ~~products and~~ product candidates; • ~~successfully identify new~~ **acquisition or in-licensing opportunities; • launch commercial sales of future** product candidates ~~through, whether alone or~~ **or discovery efforts in collaboration with others, including establishing sales, marketing and distribution systems** ~~advance those product candidates into preclinical studies and clinical trials;~~ • successfully grow our healthcare technology Vants and market the products and services offered by those Vants; • ~~raise additional funds when needed and on terms acceptable to us;~~ • attract and retain experienced management and advisory teams; • add operational, financial and management information systems and personnel, including personnel to support clinical, preclinical manufacturing and commercialization efforts and operations; • ~~launch commercial sales of future product candidates, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems;~~ • initiate and ~~continue~~ **maintain** relationships with third-party suppliers and manufacturers and have commercial quantities of products and product candidates manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements; **Table of Contents** • 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; • ~~raise additional funds when needed and on terms acceptable to us;~~ • **successfully identify new product candidates through our discovery efforts and advance those product candidates into preclinical studies and clinical trials;** and • maintain, expand and protect our intellectual property portfolio. If we cannot successfully execute on these objectives, our business may not succeed and the price of our ~~Common~~ **common Shares** ~~shares~~ may be negatively impacted. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict when and if our products and product candidates will achieve various milestones in their clinical development, including marketing approval from the FDA or other regulatory authorities, the timing or amount of increased expenses related to these activities or when we will be able to generate ~~meaningful~~ **significant** revenues ~~or achieve~~ or maintain profitability ~~, if ever~~. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities to perform studies or clinical trials in addition to those that are currently anticipated or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development in the U. S. or another jurisdiction, or if there are any delays in any of our or our future collaborators’ clinical trials or the development of our product candidates that we may identify. We anticipate incurring significant costs associated with ~~the continued commercializing~~ **commercialization of** VTAMA and ~~that of~~ any future product candidates, if approved, and advancing our ongoing clinical trials and discovery efforts until our ~~revenue~~ **revenues** from product sales of VTAMA and any other approved products exceeds such expenses, which may never occur. We may never achieve ~~sustained~~ **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., **and submitted an sNDA to the FDA for VTAMA for the topical treatment of AD in adults and children 2 years of age and older,** we have ~~not~~ **received** marketing approval for any of our other product candidates anywhere in the world and we have not generated significant product revenues from the commercial sale of our biopharmaceutical products. We cannot estimate with precision the extent of our future losses. Since inception, we have incurred significant losses and negative cash flows from operations. As of March 31, ~~2023~~ **2024**, we had cash ~~and~~ **cash equivalents and restricted cash** of approximately \$ ~~1.6~~ **7.6** billion and ~~retained earnings~~ **an accumulated deficit** of approximately \$ ~~3.576~~ **8.2** billion ~~million~~. We may never be able to develop ~~or successfully commercialize~~ **new marketable drugs** ~~successfully commercialize a marketable drug~~ or achieve **sustained** profitability. To ~~become~~ **achieve sustained profitable** profitability, 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. **and we have submitted an sNDA to the FDA for VTAMA for the topical treatment of AD,** we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize VTAMA for other indications or in other jurisdictions. Even if we achieve profitability **from product revenues** in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, expand our pipeline, market our products and, if approved, product candidates, and continue our operations. ~~Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.~~ We may never generate meaningful product revenue from the commercial sales of our products or, if approved, product candidates or achieve or maintain profitability. It is possible that we will ~~continue to~~ incur substantial operating losses for the foreseeable future. Our ability to generate meaningful product revenue and achieve **sustained** profitability is dependent on our ability to complete the development of our products and product candidates, obtain necessary regulatory approvals for our current and future ~~products and~~ product candidates and manufacture and successfully market our current and future products ~~and product candidates~~ alone or in collaboration with others. We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able **Table** to successfully market our products, acquire or in-license new products or product candidates, complete the development and commercialization of **Contents** ~~We~~ our products and product candidates and continue to pursue our drug discovery efforts. Acquiring or in-licensing, discovering, developing, commercializing and marketing biopharmaceutical products and product candidates is expensive and time consuming, and we expect to require additional capital to pursue these activities. We are also responsible for payments to third parties under our license and acquisition agreements, including milestone and royalty payments. Because of the inherent uncertainties in these activities—including the outcome of preclinical and clinical trials and the regulatory approval process—we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our current and future products and product candidates. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to: • the time and costs necessary to complete our ongoing, planned and future clinical trials; • the time and costs necessary to pursue regulatory approvals for our current and future product candidates; • the costs associated with future acquisitions or in-licensing transactions; • the approval, progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner for our ongoing and planned clinical trials and potential future clinical trials; • the costs associated with our ongoing, planned and future preclinical studies and other drug discovery activities; • our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations (“CMOs”); • the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our products and product candidates; • our ability to successfully commercialize VTAMA, including: • the manufacturing, selling and marketing costs associated with VTAMA, including the cost and timing of expanding sales and marketing capabilities or entering into strategic collaborations with third parties; and • the amount and timing of sales and other revenues from VTAMA, including the sales price and the availability of adequate third-party reimbursement; • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, including current and future patent infringement actions brought against third parties; • the cost of pursuing and defending potential intellectual property disputes, including patent infringement actions with third parties relating to our current or future products or product candidates; and • our ability to hire, attract and retain qualified personnel. We cannot be certain that additional capital will be available to us or the Vants on acceptable terms, or at all. If we or the Vants are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have **relatively** ~~to significantly delay, scale back or.....~~ and results of operations. We have limited experience as a commercial ~~-stage~~ **stage** 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 **relatively** limited experience as a commercial ~~-stage~~ **stage** company and therefore face significant risks and uncertainties relating to the commercialization of VTAMA and any future products that receive marketing approval in the U. S. or another jurisdiction, including: • our ability to recruit and retain effective sales, marketing and customer service personnel; • our ability to obtain and retain access to physicians or persuade adequate numbers of physicians to prescribe VTAMA and any future products; • the inability to manufacture and to price VTAMA and any future products at a price point sufficient to ensure

an adequate and attractive level of profitability; • the extent to which coverage and adequate reimbursement for VTAMA and any future products will be available from government health administration authorities, private health insurers and other organizations; • the risks associated with potential co-promotion or partnership agreements, including the failure to realize the expected benefits of such arrangements; • **the costs and other risks associated with expansion of a commercial product into multiple indications, including increased sales and marketing costs;** and • other unforeseen costs, expenses and risks associated with the commercialization of biopharmaceutical products, including compliance costs. In ~~addition~~ **February 2024**, ~~in connection with our continued commercialization of~~ **we submitted an sNDA to the FDA for** VTAMA ~~for~~, we expect to continue to increase the amount **topical treatment** of cash we spend in **AD for adults and children 2 years of age and older** to expand our commercial infrastructure. To the extent that we ~~are able to gain~~ **receive FDA approval for VTAMA in that indication, or receive** regulatory approval for VTAMA **or any of our future products or product candidates** in any other ~~jurisdiction~~ **jurisdictions** 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 **associated with those commercial activities**. Our **relatively** limited experience as a commercial-stage company means that there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry, ~~including those outlined herein~~. Further, given our **relatively** limited experience of commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. As we continue to develop and seek regulatory approval of additional products and product candidates, as well as additional indications for VTAMA, and to pursue regulatory approvals for VTAMA and other products and product candidates outside the U. S., it could be difficult for us to obtain and devote the resources necessary to successfully ~~manage~~ **pursue** 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 **or** to achieve profitability, which will materially affect our business, prospects, financial condition and results of operations. Our inability to successfully commercialize VTAMA or the failure of any of our product candidates in ongoing or future clinical trials or preclinical studies, in addition to having a direct adverse impact on our business and prospects, could also have a lasting negative impact on our reputation, which could, in turn, impact our ability to successfully enter into future licensing arrangements or other transactions with potential counterparties, raise future capital or attract key personnel to join us. **Our** ~~As a result, our~~ business and prospects would be materially harmed **by any such failures** and our results of operations and financial condition would likely suffer materially **as a result**. Our business is dependent to a significant extent on the successful commercialization of VTAMA and the development, regulatory approval, ~~and commercialization of~~ our current **and future products and** product candidates. We currently have one product approved by the FDA ~~—~~: VTAMA, which was approved for the treatment of plaque psoriasis in adults in the U. S. **in May 2022. In February 2024, we submitted an sNDA to the FDA for VTAMA for the topical treatment of AD for adults and children 2 years of age and older.** The success of our business, including our ability to ~~finance our company and~~ generate any **substantial revenue revenues** in the future, will depend to a significant extent on the successful commercialization of VTAMA and the successful development, regulatory approval, ~~and commercialization of~~ our other **current and future products and** product candidates. The commercial success of VTAMA and the clinical and commercial success of our other **current and future products and** product candidates will depend on a number of factors, including the following: **Table of Contents** • our ability to successfully implement and execute on a marketing strategy for VTAMA and to commercialize any of our **current or future product products candidates** in the ~~United States~~ **U. S.** and internationally, ~~if approved~~, whether alone or in collaboration with others; • acceptance by physicians, payers, ~~and patients of the benefits, safety, and efficacy of VTAMA or any of our current or future product products candidates, if approved~~, including relative to alternative and competing treatments; • timely completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors; • whether we are required by the FDA or ~~similar~~ foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our ~~current product candidates or any future products or~~ product candidates; • acceptance of our proposed indications and primary and secondary endpoint assessments relating to the proposed indications of our **current or future products or** product candidates by the FDA and ~~similar~~ foreign regulatory authorities; • the prevalence, duration, ~~and severity of potential side effects or other safety issues experienced with VTAMA or our current or future products or~~ product candidates; • the timely receipt of necessary marketing approvals from the FDA and ~~similar~~ foreign regulatory authorities **for our current or future products or product candidates**; • achieving, maintaining, ~~and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to VTAMA or any of our current or future products or~~ product candidates; • the willingness of physicians and patients to utilize or adopt VTAMA and **any of our current or future products or** product candidates, if approved; • the ability of third parties upon which we rely to manufacture clinical trial and commercial supplies of VTAMA or any of our **current or future products or** product candidates to remain in good standing with relevant regulatory authorities and to develop, validate, ~~and maintain commercially viable manufacturing processes that are compliant with Current Good Manufacturing Practice (“cGMP”)~~; • the availability of coverage and adequate reimbursement from private third-party payers and governmental healthcare programs **for VTAMA and any of our current or future products or product candidates**, such as Medicare and Medicaid; • patient demand for **VTAMA and any approved of our current or future products or product candidates**; • our ability to establish and enforce intellectual property rights in and to any **of our** current ~~and or~~ future products ~~and or~~ product candidates; • our ability to avoid third-party patent interference, intellectual property challenges, ~~or intellectual property infringement claims;~~ and • the ability to raise any additional required capital on acceptable terms, or at all. Further, competitors who are developing products in the dermatology field or that target the same indications as us with products that

have a similar mechanism of action may experience problems with their products that could indicate or result in class-wide problems or additional requirements that would potentially harm our business. Due to these risks and uncertainties, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of VTAMA or **any of our current or future products or** product candidates ~~or any future product candidates to continue achieve our~~ **or business maintain profitability**. We may not be successful in our efforts to acquire or in-license new product candidates, **and newly acquired or in-licensed product candidates may not perform as expected in clinical trials or be successful in eventually achieving marketing approvals**. ~~The Table of Contents~~ The success of our business depends in large part on our ability to successfully identify new product candidates, ~~whether generally~~ 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~~ **Once identified, we typically seek to in-license these assets from partners for low or no upfront payment, with future royalty or milestone payments to the licensor tied to the successful achievement of pre-specified development or commercialization benchmarks. From time to time, we also use joint venture structures for our Vants, where the licensor receives a minority equity ownership stake in the Vant formed around an in-licensed asset. Certain potential licensors may be unwilling or unable to pursue these types of transaction structures, which could have the effect of limiting the number of available in-licensing candidates or make us a less attractive partner for a given asset, relative to other potential acquirors. Following the acquisition or in-licensing, our** strategy often entails designing low-cost studies **for a product candidate** that result in a quick “go/no-go” ~~decisions~~ **decision on** 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 the~~ **of that study** and later determine that the more costly and time-intensive trials **required for regulatory approvals** do not support the initial value the product candidate was thought to hold **or demonstrate the product profile required for a marketing approval**. Even if a product candidate does prove to be valuable **or successful in receiving marketing approval**, its value may be less than ~~we~~ anticipated at the time of ~~the~~ investment, **including after payments of applicable royalty and milestone payments to the licensor, and we may not be able to recover our investment into the development of the product candidate**. We may also face **significant** competition for attractive investment opportunities. A number of ~~entities~~ **companies** compete with us for such opportunities, ~~many some~~ of which ~~have considerably~~ **may possess** greater financial ~~and or~~ technical resources. If we are unable to identify a sufficient number of ~~such potential~~ product candidates **for acquisition or in-licensing**, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to **successfully develop generate returns and implement our** ~~or investment strategy~~ **receive marketing approval for those product candidates**, and our business and results of operations may suffer materially **as a result**. Any such failure to in-license or acquire new product candidates from third parties, **or the failure of those product candidates to succeed in clinical trials and eventually receive marketing approval**, would have a material adverse effect on our business, financial condition, results of operations and prospects. ~~Our drug discovery efforts may not..... successfully discovered product candidates may be limited~~. We face risks associated with the allocation of capital and personnel across our businesses. Because we have ~~limited finite~~ financial and management resources, we have to make challenging decisions regarding the allocation of capital and personnel across our businesses. We face certain risks associated with these decisions and may fail to capitalize on viable commercial product candidates or profitable market opportunities. For example, we may decide not to pursue a particular in-licensing or acquisition opportunity, or a potential target indication for a product candidate, that later proves to have greater commercial potential than our current and planned development programs and product candidates. Similarly, our management’s attention to one product 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, **legal** and human resources expertise. Efforts to do so may not result in the actual acquisition or in-license of a successful product candidate, potentially resulting in a diversion of our management’s time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment, **would have a material adverse effect on our business, financial condition, results of operations and prospects**. We face risks associated with the Vant structure. Our products and product candidates are developed at our Vants, which operate similarly to independent biopharmaceutical companies **with their own management teams and equity incentive structures**. While we believe that there are significant competitive advantages to this structure, as compared to traditional pharmaceutical companies or smaller biopharma companies, the Vant structure also poses certain risks for our business. ~~Operating~~ **Table of Contents** ~~Operating~~ the Vants independently, rather than under a centralized, consolidated management team, may result in increased costs at **Roivant and** the Vants, as certain functions or processes, including sales and marketing, clinical and nonclinical personnel, business development, finance, accounting, human resources and legal functions, are replicated ~~across the~~ **at Roivant and at multiple** Vants. There may also be certain start-up costs, associated with the establishment of a new Vant or integration of a newly acquired business into a Vant, which are greater under the Vant model than they would be under a centralized model. The use of the Vant model may also entail increased costs for us, including the time and expenses associated with hiring Vant CEOs and management teams, overseeing Vant equity incentive arrangements and managing compliance-related risks, including the internal controls,

reporting systems and procedures necessary for us to operate as a public company. We may also be exposed to increased “key employee” risks, in the event a Vant CEO were to depart, including the loss of other senior Vant personnel, potentially resulting in adverse impacts to commercialization or development work at the Vant. These increased expenses, complexities and other challenges may make using and scaling the Vant model more challenging and costly than it would be for a traditional pharmaceutical company to both operate and expand the number of product candidates under development, which could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects. This decentralized model could also make compliance with applicable laws and regulations more challenging to monitor and may expose us to increased costs that could, in turn, harm our business, financial condition, results of operations or prospects. In addition, a single or limited number of the Vants may, now or in the future, comprise a large proportion of our value. Similarly, a large proportion of our consolidated revenues may be derived from one or a small number of Vants. For example, our only approved product, VTAMA, was developed and is being commercialized by Dermavant, one of our Vants. Any adverse development at Dermavant or any other Vant, including the loss of key members of management, the termination of a key license agreement or other loss of the intellectual property underlying a product or product candidate or the failure of a clinical trial for a product candidate under development at the Vant, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects. We do not wholly own many of our Vants. **Our Vants have equity incentive plans, which can dilute our ownership interest in the Vant as those awards vest and are exercised**, and certain of our Vants have issued debt or equity securities senior to our ownership interests, which dilutes our economic interest in the Vants **and can in certain cases, such as our publicly traded subsidiary Immunovant, limit our operational control of the Vant**. **The vesting and exercise of incentive equity awards at the Vants, as well as** Future future capital needs at individual the Vants **– which** may also be financed through senior debt or equity securities, or common equity **– all of which** may further dilute our **or subordinate our ownership and economic interest interests in a the Vants or reduce our operational control of the Vants. In addition, recipients of Vant equity awards may have economic alignment with a Vant that incentivizes them to act in ways that prioritize the success of a Vant over the success of the Company as a whole, which could adversely impact our consolidated business, financial condition, results of operations or prospects**. **For more information on our ownership of our Vants, see “Business – Overview – Vant Ownership.”** We manage the Vants in part through our designees who serve on the Vant boards of directors. In their capacities as directors, those individuals may owe fiduciary duties to the Vants and their shareholders under applicable law, which may at times require them to take actions that are not directly in our interest **as a shareholder**. To the extent any such actions have an adverse effect on the value of our ownership interest in the Vant, it could further adversely impact our consolidated business, financial condition, results of operations or prospects. We face risks associated with potential future payments related to our products and product candidates. Our asset in- licensing transactions typically involve zero or low upfront payments combined with milestone and royalty payments. These arrangements generally involve a payment or payments upon the achievement of certain development or regulatory milestones, including regulatory approval, and then royalty payments upon the achievement of specified levels of sales, which can extend for up to the life of a product. Some of these payments may become due before a product is generating revenues, **in which case we may not have sufficient funds available to enable us** to meet our obligations. If this were to occur, we would default on our payment obligations and could face penalties, delays in commercialization or development activities, **the termination of a license agreement** or reputational damage. Even for a product that is commercialized and generating revenue, payments could become due that are so large that the investment is not profitable or is less profitable than anticipated. For example, this could occur if at the time of the initial investment, we overestimated the value of the product and agreed to a payment schedule using these inflated estimates. If we are unable to make milestone and royalty payments related to our product candidates when due, our business and prospects could suffer and our ability to in- license future product candidates could be impaired. Our business strategy and potential for future growth relies on a number of assumptions, some or all of which may not be realized. Our business strategy and plans for future growth rely on a number of assumptions, including, in the case of our products and product candidates, assumptions related to adoption of a particular therapy, incidence and prevalence of an indication, use of a product or product candidate versus competitor therapies and size of the addressable patient populations. Some or all of these assumptions may be incorrect **due to errors or mistaken assumptions in our analysis or the inherent uncertainties in the drug development process, among other reasons**. We cannot accurately predict whether 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 Table of Contents We** may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, including acquisitions or divestitures of companies, asset purchases or sales and out-licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spinoffs, strategic partnerships, joint ventures, collaborations, restructurings, divestitures, business combinations and investments. **For example, in December 2023, we completed a transaction to sell Telavant, which was owned by us and Pfizer, to Roche for aggregate upfront consideration of \$ 7.1 billion and a near- term, one- time milestone payment of \$ 150 million (the “Roche Transaction”).** Any future transactions could increase our near- and long- term expenditures, result in potentially dilutive issuances of our or our Vants’ equity securities, including our **Common common Shares shares**, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, and could expose us to the risk of litigation, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions, **which may or may not include using all or a portion of the cash proceeds from the Roche Transaction as consideration**, may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful

and may require significant time and attention of our management, as well as significant costs, whether or not successfully consummated. In addition, the integration **or separation** of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the **acquisition transaction**. For any alliances or joint ventures that we enter into in the biopharmaceutical industry, we may encounter numerous difficulties in discovering, developing, manufacturing and marketing any new products or product candidates related to such businesses, which may delay or prevent us from realizing the expected benefits or enhancing our business. Divestiture transactions, ~~if such as they~~ **the Roche Transaction** ~~were to occur~~, may adversely impact the price of our common shares, to the extent investors believe the value of the consideration received in the transaction is not equivalent to the value of the asset or program divested. Accordingly, ~~although there can be no assurance that we will undertake or successfully complete any additional~~ **transactions of the nature described above will be undertaken or successfully completed**, ~~and that any additional transactions~~ **transaction that we do complete could will not** have a material adverse effect on our business, results of operations, financial condition and prospects. **We face risks associated with the use of our cash, cash equivalents and restricted cash, including any return of capital to shareholders. As of March 31, 2024, we had cash, cash equivalents and restricted cash of approximately \$ 6. 6 billion, which includes the cash proceeds from the Roche Transaction. Our management team has broad discretion in respect of use of our cash, cash equivalents and restricted cash, including the proceeds from the Roche Transaction. We may use all or a portion of such proceeds for one or more strategic transactions, including acquisitions of companies, asset purchases or sales or in- licensing of intellectual property, products or product candidates or technologies, as described above. We may not be able to find a suitable strategic transaction that we deem sufficiently attractive to pursue, and may not be able to complete a strategic transaction in the future. Our ability to complete a strategic transaction may be negatively impacted by general market conditions, volatility in the capital markets and the other risks described herein. We may also decide to return capital to shareholders through one or a combination of public or private share repurchases, or the issuance of cash dividends on our common shares. As previously disclosed, our board of directors has authorized a common share repurchase program, allowing for repurchases of common shares in an aggregate amount of up to \$ 1. 5 billion (excluding fees and expenses) (the “ 2024 Repurchase Program ”). A portion of the 2024 Repurchase Program, approximately \$ 648. 4 million, was used to repurchase all of the common shares held by Sumitomo Pharma Co., Ltd. in April 2024. The timing and total amount of any additional common shares repurchased under the 2024 Repurchase Program or any future repurchase authorization from our board of directors will depend on several factors, including the market price of our common shares, general business, operations macroeconomic and market conditions** ~~clinical development timelines are subject to risks arising from the COVID- 19 pandemic and other investment opportunities~~ ~~epidemic diseases. The COVID- 19 worldwide pandemic has presented substantial public health and economic challenges and has affected our employees, patients, physicians and other healthcare providers, communities and business operations~~, as well as the U. S. **discretion of our board of directors, or its delegates, that any such activity would be in the best interests of our shareholders and global economies in compliance with all applicable laws and our contractual obligations. In the event that we decide to pursue further repurchases of common shares, we may be limited in our ability to repurchase our common shares by various governmental laws, rules and regulations which prevent us from purchasing our common shares during periods when we are in possession of material non- public information. We may also use our discretion to repurchase common shares from certain shareholders without offering the opportunity to all shareholders to have their common shares repurchased at that time and price. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. Table of Contents** ~~The amount of cash available to return to shareholders, if any, can vary significantly from period to period for a number of reasons, including, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. The returns of capital to shareholders may change in form, amount, value and frequency from time to time, and we cannot guarantee that any such future returns of capital will take place. The trading price of our common shares may decline, possibly materially, if we are unable to meet investor expectations with respect to the timing and total amount of future capital returns to shareholders. There is no guarantee that our significant balance of cash, cash equivalents and restricted cash, including the proceeds from the Roche Transaction, will be used to increase our operating results, return capital to shareholders or enhance the value of our common shares. We are exposed to risks related to our significant holdings of cash, cash equivalents and restricted cash. Our significant holdings of cash, cash equivalents and restricted cash can be negatively affected by changes in liquidity, financial results, markets- market~~ ~~International and U- economic conditions, political risk, currency risk, credit risk, sovereign risk, interest rate fluctuations or other factors~~ ~~S- As a result, the value and liquidity of our cash, cash equivalents and restricted cash may fluctuate substantially~~ ~~governmental authorities in impacted regions~~ ~~Additionally, we may from time to time have taken~~ ~~balances in bank accounts that are in excess of insured deposit limits~~ ~~and could be subject to risks of bank failures. Therefore, although we have not realized any significant losses on our cash, cash equivalents and restricted cash, future fluctuations in their value could result in significant losses and could have a material adverse impact on our results of operations and financial condition. We may require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to successfully 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~~ ~~take actions in an effort- efforts~~ ~~. Acquiring or in- to slow the spread of COVID- 19- licensing, discovering, developing, commercializing and variants of marketing biopharmaceutical products and product candidates is expensive and time consuming, and, in the future, we may require additional capital to pursue~~ ~~the these virus activities~~ ~~. The continued spread~~ **We are also responsible for payments**

to third parties under our license and acquisition agreements, including milestone and royalty payments. Because of COVID-19 the inherent uncertainties in these activities – including the outcome of preclinical and clinical trials and the regulatory approval process – we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of our current and future products and product candidates. Our future funding requirements, both near- and long- term, the measures taken by governmental authorities, and will depend on any many factors, including, but not limited to: • the time and costs necessary to complete our ongoing, planned and future epidemic clinical trials or for pandemic disease outbreaks, may cause disruptions that could severely impact our current and future products and product candidates; • the time and costs necessary to pursue regulatory approvals for our current and future product candidates; • the costs associated with future acquisitions or business-in- licensing transactions; • the approval, progress, timing, scope and costs of our preclinical studies, clinical trials and financial condition other related activities, including by- the ability to enroll patients in a timely manner for our ongoing and planned clinical trials and potential future clinical trials for our current and future product candidates; • disrupting the costs associated with our ongoing, planned and future preclinical studies and the other drug discovery activities; • our ability to successfully identify and negotiate acceptable terms for third- party supply chain and the contract manufacture manufacturing or shipment agreements with contract manufacturing organizations (“ CMOs ”); • the costs of drug substances obtaining adequate clinical and finished commercial supplies of raw materials and drug products for our current and future products and product candidates for use in our research, preclinical studies and clinical trials; • delaying, limiting or our preventing ability to successfully commercialize VTAMA, including: o the manufacturing, selling and marketing costs associated with VTAMA, including the cost and timing of expanding sales and marketing capabilities our- or employees entering into strategic collaborations with third parties; and- ando CROs the amount and timing of sales and other revenues from continuing research VTAMA, including the sales price and development activities the availability of adequate third- party reimbursement; Table of Contents • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights, including current and future patent infringement actions brought against third parties, for our current and future product candidates ; • impeding the cost of pursuing and defending potential intellectual property disputes, including patent infringement actions with third parties, relating to our current our- or clinical trial initiation future products or product candidates; and • our recruitment and the ability to hire, attract and retain qualified personnel. In the event that we require additional financing, we cannot be certain that additional capital will be available to us or the Vants on acceptable terms, or at all. If we or the Vants are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our in- licensing and acquisition, discovery, development, commercialization and marketing activities. In addition, attempting to secure additional capital may divert the time and attention of patients time and attention of our management from day- to- day activities and harm our business. Because of the numerous risks and uncertainties associated with our business, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and future product development programs and discovery efforts. Moreover, risks associated with broader market conditions, including high levels of inflation, rising heightened interest rates and increasing market and banking sector instability and volatility, all of which have been observed in recent periods, may further adversely impact our ability to obtain financing on acceptable terms or at all. We expect that In the future, we may require significant additional capital to continue our operations, pursue business opportunities or strategic transactions, or respond to challenges, competition or unforeseen circumstances. Until such time, if ever, that we can generate substantial revenues, we may finance future cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations at Roivant and the Vants. To the extent that we raise additional capital by issuing equity securities at Roivant or the Vants, our existing shareholders’ ownership, or our ownership in clinical trials 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 the risk that participants enrolled potential acquisitions. If adequate funds are not available to us, we may be required to forego potential in our clinical trials will contract COVID- 19 while the clinical trial is ongoing 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 impact the results of the clinical trial, including by increasing the number of observed adverse events; • impeding testing, monitoring, study procedures (such as endoscopies that are deemed non- essential), data collection and analysis and other related activities that may impact the integrity of subject data and clinical study endpoints; and • affecting --- affect the our business of the FDA, prospects European Medicines Agency (“ EMA ”) or other regulatory authorities, which could result in delays in meetings related to ongoing or planned clinical trials. The extent to which the COVID- 19 pandemic or any future pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus, the identification of new variants, the rate of vaccine administration and the actions taken to contain its impact. The FDA issued a number of guidance documents describing its expectations for how drug manufacturers should comply with various FDA

requirements during the COVID-19 pandemic and has otherwise exercised enforcement discretion as to certain requirements due to the related public health emergency. The determination that a public health emergency exists issued by the U. S. Department of Health and Human Services (“HHS”) Administration for Strategic Preparedness and Response under Section 319 of the Public Health Service Act (“PHSA”) ended on May 11, 2023, and the determination that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad issued by HHS under Section 564 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) may end in the near term. In anticipation of these events, the FDA published a notice in the Federal Register indicating which guidance documents will immediately cease upon termination of the emergency declaration under the PHSA as well as those that will be revised or continue for a limited or indefinite time. As a result, we may assume a greater compliance burden in connection with our ongoing clinical trials. The COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. To the extent the COVID-19 pandemic or any future pandemic adversely affects our business and financial results, it may also have the effect of **operations** heightening many of the other risks described in this section. We may not be able to complete certain strategic transactions if a proposed transaction may be subject to review or approval by regulatory authorities pursuant to certain U. S. laws or regulations. Certain potential acquisitions, **divestitures** or **other** business combinations that we may pursue could be subject to review or approval by regulatory authorities pursuant to certain U. S. laws or regulations. In the **United States U. S.**, certain mergers that potentially could affect competition may require certain filings and review by the Department of Justice and the Federal Trade Commission. In recent years, there has been enhanced regulatory scrutiny over such transactions. In the event that we were to make an investment, acquisition or disposition that was determined to be subject to regulatory review, and such regulatory approval or clearance is not obtained, or the review process is extended beyond the period of time that would permit such strategic transactions to be consummated, we may not be able to consummate such strategic transactions or counterparties may be deterred from pursuing potential strategic transactions with us. This may impair our ability to raise capital when needed and to pursue accretive transactions, which is an important part of our business model, and have an adverse effect on our business, financial condition and prospects. **Our Table of Contents** Our drug discovery efforts may not be successful in identifying new product candidates. Our drug discovery efforts are centered on our discovery Vants, including Psivant, **Covant, Mviant, Proteovant** and VantAI, which employ a variety of approaches to the drug discovery process, including quantitative proteomics, induced proximity, **targeted protein degradation** and covalency. As a company, we have relatively limited experience in drug discovery generally and with certain of the computational tools that are employed in those efforts. Our future success depends, in part, on our ability to successfully use these approaches and technologies to identify promising new product candidates and eventually advance those product candidates through preclinical studies and clinical trials. We have not yet succeeded and may not succeed in advancing any product candidates developed through these discovery efforts into clinical trials, demonstrating the efficacy and safety of such product candidates or obtaining regulatory approval thereafter. As a result, it is difficult to predict the time and cost of product candidate development from our discovery Vants and we cannot predict whether the application of these approaches will result in the development and regulatory approval of any products. In addition, many of the active drug discovery efforts at our discovery Vants are being conducted pursuant to collaboration agreements with third parties, in which the third parties are either owed milestone and royalty payments tied to the successful development and commercialization of successfully identified drug candidates, or have been granted exclusive or shared development and commercialization rights with respect to successfully identified drug candidates in exchange for upfront payments, shared expenses, and certain milestone and royalty payments owed to the discovery Vants. Any problems that we or our third party partners experience in the future related to this platform or any of our related development programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any internally discovered product candidates we may develop on a timely or profitable basis, if at all. Even if successful, as a result of our collaboration agreements, our rights to commercialize any successfully discovered product **candidates may be limited**. Risks Related to the Development of Our 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 **accepted for review or ultimately** approved by the relevant regulatory authorities. Clinical trials and preclinical studies are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA, an institutional review board (“IRB”), an Ethics Committee (“EC”) or other regulatory authorities may not agree with the proposed analysis plans or trial design for the clinical trials of our product candidates, and during any such review, may identify unexpected efficacy or safety concerns, which may delay the effective date of an IND or approval of an NDA, BLA or similar application. The FDA, the European Medicines Agency (“EMA”), the European Commission, the Medicines and Healthcare product Regulatory Agency (“MHRA”) or other relevant regulatory authority may also find that the benefits of any product candidate in any applicable indication do not outweigh its risks in a manner sufficient to grant regulatory approval. The FDA or other regulatory authorities may also not



agree with the scope of our proposed investigational plan. For example, they may find that our proposed development program is not sufficient to support a marketing authorization application, or that the proposed indication is considered to be too broad. Moreover, the FDA or other regulatory authorities may also refuse or impose certain restrictions on our reliance on data supporting our clinical trial application or marketing authorization application should such data originate from studies outside of the relevant jurisdiction or be affected by regulatory non-compliance, including issues of data integrity. In the EU, data derived from clinical trials that were conducted outside the EU cannot be used to support a CTA unless the clinical trial was registered on a relevant database. In each case, this could delay the clinical development and authorization timeline for a given product candidate. Failures can occur at any stage of development, including clinical trials or preclinical studies, and we could encounter problems that cause us to abandon or repeat clinical trials or preclinical studies. In addition, results from clinical trials or preclinical studies may require further evaluation, delaying the next stage of development or submission of an IND or an NDA or similar application in the U. S. or another jurisdiction. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having successfully progressed through preclinical and earlier stage clinical trials. Such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in earlier studies or trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in, or the discontinuation of, advanced clinical trials with a product candidate due to lack of efficacy or adverse safety findings, despite having promising results in earlier trials or studies. Likewise, the results of early clinical trials or preclinical studies of our product candidates may not be predictive of the results of **current or** future development programs. There can also be no assurance that the results of studies conducted by collaborators or other third parties with similar product candidates in similar indications will be viewed favorably or indicative of our own future trial results. **The Table of Contents** The commencement and completion of preclinical studies and clinical trials may be delayed by several factors, including: • failure to obtain regulatory authorization to commence a clinical trial or reaching consensus with regulatory authorities regarding the design or implementation of our studies; • other regulatory issues, including the receipt of any inspectional observations on FDA's Form- 483, Warning or Untitled Letters, clinical holds, or complete response letters or similar communications / objections by other regulatory authorities; • unforeseen safety issues, or subjects experiencing severe or unexpected adverse events; • occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; • lack of effectiveness during clinical trials; • resolving any dosing issues, including those raised by the FDA or other regulatory authorities; • inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial; • failure to add a sufficient number of clinical trial sites; • unanticipated impact from changes in or modifications to protocols or clinical trial design, including those that may be required by the FDA or other regulatory authorities; • inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements; • an IRB or EC refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; • premature discontinuation of study participants from clinical trials or missing data; • failure to manufacture or release sufficient quantities of our product candidates or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials; • inability to monitor patients adequately during or after treatment; or • inappropriate unblinding of trial results. **We** ~~In addition, disruptions caused by the ongoing effects of the COVID-19 pandemic or future pandemics may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.~~ Further, we, the FDA or other regulatory authorities may suspend our clinical trials in an entire country at any time, or an IRB / EC may suspend our clinical trial sites within any country, if it appears that we or our collaborators, or the principal investigator, are failing to conduct a trial in accordance with the protocol, applicable regulatory requirements, including Good Clinical Practice ("GCP") regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority finds deficiencies in our IND or equivalent applications for other countries or in the manner in which clinical trials are conducted. **In addition, disruptions caused by any ongoing effects of the COVID-19 pandemic or future pandemics may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.** Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of our product candidates, if approved, may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause or lead to a termination or suspension of, or delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical or clinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring product candidates to market before we do, and the commercial viability of our product candidates could be significantly reduced. **Moreover, Table of Contents** **Moreover**, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other

regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing and authorization applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of any of our product candidates. In addition, for our products or product candidates that are in clinical development, prior to our acquisition of the rights to those products or product candidates we had no involvement with or control over the preclinical or clinical development of those products or product candidates. We are therefore dependent on our licensing and other transaction partners having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having used appropriately regulated and compliant equipment and devices during the preclinical or clinical development, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to those products or product candidates, having correctly collected and interpreted the data from these trials and other research and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these products or product candidates. Problems associated with the pre-acquisition development of our products or product candidates could result in increased costs and delays in the commercialization of our products or development of our product candidates, which could harm our ability to generate any future revenue from sales of products or, if approved, product candidates. We may encounter difficulties enrolling and retaining patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected. We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials for our products or product candidates on current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical trials for these products or product candidates. Enrollment in our clinical trials may also be slower than we anticipate, or be stopped, leading to delays in the development timelines for our products and product candidates. Patient enrollment and retention in clinical trials depends on many factors, including EC approval of patient participation as proposed, the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors, including those related to the any ongoing effects of COVID-19 pandemic or future pandemics, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents and our ability to successfully complete prerequisite studies before enrolling certain patient populations. For certain of our products and product candidates, including IMVT- 1402 and batoclimab, which targets target 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 Table of Contents The results of our preclinical studies and clinical trials may not support our proposed claims for our products or product candidates, or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior preclinical studies and earlier clinical trials. For example, we cannot assure you that the efficacy and safety results from our TUSCANY-2 trial of RVT-3101 in ulcerative colitis or the reductions in IgG antibodies that we have and favorable analyte profile observed to date in our clinical Phase I trials - trial and preclinical studies of batoclimab and IMVT- 1402 and will be observed in future clinical trials, including pivotal trials necessary for regulatory approvals. Likewise, promising interim results or other preliminary analyses do not ensure that the clinical trial as a whole will be successful and may lack statistical significance, which would further limit the reliability of such interim or preliminary data. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in, or the discontinuation of, clinical trials, even after promising results were seen with their product candidates in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unobserved adverse events. The results of preclinical studies and early clinical trials of our products and product candidates may not be predictive of the results of later-stage clinical trials. Products and product candidates in later stage clinical trials may fail to show the desired safety and efficacy traits despite having progressed through

preclinical and initial clinical trials. A future failure of a clinical trial to meet its pre-specified endpoints may cause us to abandon development of the product candidate in question. Any delay in, or termination of, our clinical trials will prevent or delay the submission of an NDA or other similar applications to the FDA or other relevant comparable non-U.S. regulatory authorities and, ultimately, our ability to commercialize our products or, if approved, our product candidates, and generate product revenues. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our products and product candidates. The FDA and other regulatory authorities, including the EMA and the MHRA, have substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of product candidates under development result in the submission of an NDA or other similar application to the FDA and other comparable non-U.S. regulatory authorities and even fewer are approved for commercialization. Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, and in some countries, in line with the applicable requirements set out in legislation and guidance, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data. For example, earlier this year we previously disclosed 24-week interim and chronic period data from the TUSCANY our NEPTUNE trial of brepocitinib in non- anterior non- infectious uveitis, results from the initial cohort of patients in our Phase 2 trial of batoclimab RVT-3101 in ulcerative colitis Graves' disease and initial human top-line data from our pivotal atopic dermatitis Phase 3 ADORING-1 and ADORING-2 trials- trial of VTAMA IMVT- 1402. These results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously reported. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us or by our competitors could result in increased volatility in the price of our shares. Further, other parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of a particular product or product candidate and our business in general. In addition, the information we choose or are required to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our products and product candidates, our business, operating results, prospects or financial condition may be harmed. Changes Table of Contents Changes in methods of product manufacturing or formulation may result in additional costs or delay. As our products and product candidates proceed through the development process, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause products or product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval, or another regulatory authority's notification or approval, as applicable, since similar requirements apply in other jurisdictions. This could delay the completion, or result in the abandonment, of clinical trials, require the conduct of bridging clinical trials, the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our products and product candidates and jeopardize our ability to commence sales and generate revenues. We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements, it may harm our business. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance. In addition, we rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable contract, protocol, legal, regulatory and scientific standards and that clinical trial sites meet applicable protocol and regulatory requirements. Our reliance on CROs does not relieve us of our regulatory or specified contractual responsibilities. We and our CROs are required to comply with Good Laboratory Practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and other comparable non-U.S. regulatory authorities, which also require compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines for any of our products and product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we may rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and

protocol and applicable laws and regulations. Our expected reliance on the CROs does not relieve us of our regulatory or contractual responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or non- U.S. regulatory authorities may reject our marketing authorization applications and require us to perform additional clinical trials to generate additional data before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process. Failure by any future CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies. Our CROs are independent, third- party organizations and we do not control whether they devote sufficient time, attention and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product or product candidate that we develop. As a result, our financial results and the commercial prospects for any product or product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can adversely impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with the CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

~~We~~ **Table of Contents** ~~We~~ do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of our products and product candidates. We do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Accordingly, we rely on third parties to produce commercial and clinical supplies of our products and product candidates. For example, Dermavant, ThermoFisher and GSK have entered into agreements pursuant to which ThermoFisher and GSK are providing commercial drug product and drug substance for VTAMA as well as drug product and drug substance for Dermavant’ s ~~recently~~ completed pivotal atopic dermatitis Phase 3 ADORING 1 and ADORING 2 trials of VTAMA as well as its ongoing open label long- term extension study of VTAMA in atopic dermatitis. If these counterparties do not fulfill their obligations under these agreements, Dermavant’ s ability to sell VTAMA commercially and conduct its ongoing and future clinical trials with VTAMA may be adversely impacted. Third- party vendors may be difficult to identify for our product process and formulation development and manufacturing due to special capabilities required, and they may not be able to meet our quality standards. In addition, certain of our third- party manufacturers and suppliers may encounter delays in providing their services as a result of supply chain constraints. If any third- party manufacturers or third parties in the supply chain for materials used in the production of our products or product candidates are adversely impacted by supply chain constraints, our supply chain may be disrupted, limiting our ability to manufacture our products for commercialization and products or product candidates for our preclinical studies, clinical trials and research and development activities. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, or of equipment and devices as necessary, for either commercialization or an ongoing clinical trial, due to the need to replace a third- party manufacturer or otherwise, could considerably delay marketing efforts for the product in question or the completion of clinical trials, product testing and potential regulatory approval of the product candidate in question. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our products or product candidates, the commercial launch of our products or product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products or product candidates and may require notification to the FDA or other regulatory authorities. Moreover, as a result of projected supply constraints for certain materials used in the production of our products or product candidates, we have in the past and may in the future reserve manufacturing capacity in advance of receiving required efficacy or safety results from our clinical trials, which may involve committing substantial financial resources to current or future products or product candidates that may never be approved or achieve commercialization at scale or at all. In addition, legislative, executive and regulatory proposals were recently enacted or are pending to, among other things, prevent drug shortages, improve pandemic preparedness and reduce the dependency of the ~~United States~~ **U.S.** on foreign supply chains and manufacturing. While we are still assessing these developments, they could impact our selection and utilization of CMOs, vendors and other suppliers and could have a material adverse impact on our business, financial condition and results of operations. The facilities used by our contract manufacturers to manufacture our 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; **Table of Contents**
- 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 - U.S.** These regulations govern manufacturing processes and procedures, including record- keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our 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 Table of Contents** 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.** Certain of our products and product candidates are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business. The manufacturing processes our CMOs use to produce our products and product candidates are complex, novel and, in the case of our product candidates, have not necessarily been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers. Our biologic product candidates may require processing steps that are more complex than those required for most small molecule drugs. Moreover, unlike small molecules, the physical and chemical properties of biologics generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot- to- lot or will perform in the intended manner. Accordingly, our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. We may encounter problems achieving adequate quantities and quality of clinical- grade materials that meet the FDA, the EU, the UK or other applicable standards or specifications with consistent and acceptable production yields and costs. In addition, the FDA, the EMA, the MHRA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, the MHRA or other comparable regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. **Our Table of Contents** 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..... or we could lose potential revenue.** Risks Related to Regulatory Approval and Commercialization of Our Products and Product Candidates Obtaining approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or another regulator may delay, limit or deny approval. If we are unable to obtain regulatory approval in one or more jurisdictions for any products or product candidates, our business will be substantially harmed. We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable non- U. S. regulatory authorities is lengthy and unpredictable, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of nonclinical or clinical data necessary to gain approval may change during the course of a product candidate' s development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. While we have obtained regulatory approval in the U. S. for one of our product candidates, VTAMA, for the treatment plaque psoriasis in adults, **and have submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD for adults and children 2 years of age and older**, it is possible that VTAMA will not **obtain receive this** regulatory approval **or obtain any other regulatory approvals** in the U. S. for other indications or in other jurisdictions, and that other current and future product candidates will not be successful in obtaining regulatory approval in the U. S. and other jurisdictions. In addition, we cannot be certain that any products or product candidates that receive regulatory approval will be successfully commercialized. Obtaining marketing approval of a new drug is an extensive, lengthy, expensive and inherently uncertain process and the FDA or other non- U. S. regulatory authorities may delay, limit or deny approval of a product candidate for many reasons, including: • we may not be able to demonstrate that a product candidate is safe and effective as a treatment for the targeted indications, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure and potent for use in its targeted indication, to the satisfaction of the FDA or other relevant regulatory authorities; • the FDA or other relevant regulatory authorities may require additional pre- approval studies or clinical trials, which would increase costs and prolong development timelines; • the results of clinical trials may not meet the

level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval; • the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of clinical trials, including the design of proposed preclinical and early clinical trials of any future product candidates; • the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact the clinical trials and ability to obtain marketing approvals; • the FDA or other relevant regulatory authorities may not find the data from nonclinical, preclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks; • the FDA or other relevant regulatory authorities may disagree with an interpretation of data or significance of results from nonclinical, preclinical studies or clinical trials or may require additional studies; • the FDA or other relevant regulatory authorities may not accept data generated at clinical trial sites, including in situations where the authorities deem that the data was not generated in compliance with GCP, ethical standards or applicable data protection laws; **Table of Contents** • if an NDA, BLA or a similar application is **referred for reviewed--review** by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authorities, as the case may be, require, as a condition of approval, additional nonclinical, preclinical studies or clinical trials, limitations on approved labelling or distribution and use restrictions; • the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy (“REMS”) **drug safety program** or its equivalent, as a condition of approval; • the FDA or other relevant regulatory authorities may require additional post- marketing studies and / or patient registries for product candidates; • the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates; • the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third- party manufacturers; or • the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations .~~For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA’s concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders, the FDA’s goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval. The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. Indeed, the FDA issued Draft Guidance for Industry, Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases (January 2023), to assist sponsors in identifying the optimal dosages for these products during clinical development and prior to submitting an application for approval for a new indication and usage.~~ Our future success depends significantly on our ability to successfully complete clinical trials for our product candidates, obtain regulatory approval and then successfully commercialize those product candidates. Any inability to successfully initiate, conduct or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional nonclinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from nonclinical and clinical research conducted using earlier versions of these product candidates. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize product candidates and may harm our business and results of operations. Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down the product candidate development and approval process and delay or potentially jeopardize our ability to receive regulatory approvals, commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and have a negative impact on the price of our **Common common Shares shares**. Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies, preclinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have **relatively** limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support additional marketing approvals. We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable non- U. S. regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval

in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable non- U. S. regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even when regulatory approval is secured for a product 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 Table of Contents~~Our products and product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance. Adverse events caused by or associated with our products and product candidates have caused us and could, in the future, cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our product candidates or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment- related side effects arising from, or those perceived to arise from, our product candidates or those from other companies targeting similar diseases, could also affect patient recruitment or the ability of enrolled patients to complete their participation in our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. For example, as previously disclosed, in early 2021, our subsidiary Immunovant voluntarily paused dosing in early phase clinical studies for batoclimab to evaluate treatment- induced elevations in total cholesterol and LDL levels observed in some trial subjects. After evaluation of the available safety data and following discussions with multiple regulatory agencies, Immunovant is continuing its clinical development of batoclimab. While Immunovant does not expect that increases in LDL over a short- term treatment duration would pose a safety concern for patients, the risk- benefit profile of long- term administration of batoclimab will need to incorporate any unfavorable effects on lipid profiles. These occurrences have harmed, and any reoccurrence may continue to harm our business, financial condition and prospects. Furthermore, if any of our products, or any future product candidates that are approved, cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw, **revoke**, suspend, vary, or limit their approval of the product or require a REMS (or equivalent outside the ~~United States~~U. S. ) to impose restrictions on its distribution or other risk management measures; • regulatory authorities may **request or** require that we recall a product; • additional restrictions being imposed on the distribution, marketing or manufacturing processes of the products or any components thereof, including a “ black box ” warning or contraindication on product labels or communications containing warnings or other safety information about the product; • regulatory authorities may require the addition of labelling statements, such as warnings or contraindications, require other labelling changes of a product or require field alerts or other communications to physicians, pharmacies or the public; • we may be required to change the way a product is administered or distributed, conduct additional clinical trials, change the labelling of a product or conduct additional post- marketing studies or surveillance; • we may be required to repeat preclinical studies or clinical trials or terminate programs for a product candidate, even if other studies or trials related to the program are ongoing or have been successfully completed; • we may be sued and held liable for harm caused to patients, or may be subject to fines, restitution or disgorgement of profits or revenues; • physicians may stop prescribing a product; • reimbursement may not be available for a product; • we may elect to discontinue the sale of our products; • our products may become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected products or product candidates, substantially increase the costs of commercializing our products or product candidates in the future and have a negative impact on the price of our ~~Common~~**common Shares** shares. ~~The Table of Contents~~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~~U. S. In addition, clinical trials conducted in one country, and the data generated therefrom, may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We have one product, VTAMA, which has been approved by the FDA for the treatment of plaque psoriasis in adults in the U. S. , **and have submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD**, 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. **We have also submitted an sNDA to the FDA for the approval of VTAMA for the treatment of AD.** In order to market VTAMA or any of our other products or product candidates outside of the ~~United States~~ **U. S.**, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the ~~United States~~ **U. S.**, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the ~~United States~~ **U. S.**, a product candidate must be approved for reimbursement before it can be sold in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Seeking regulatory approval outside of the ~~United States~~ **U. S.** could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time- consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The regulatory approval process outside of the ~~United States~~ **U. S.** 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.

**Table of Contents****We have one product, VTAMA, approved by the FDA for the treatment of plaque psoriasis in adults in the U. S.** We have **also submitted an sNDA to** ~~one product, VTAMA, approved by~~ the FDA for the **approval of VTAMA for the** ~~treatment of AD plaque psoriasis in adults in the U. S.~~ Any product or product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements, including for manufacturing processes, post-approval clinical data, labelling, packaging, distribution, adverse event reporting, storage, recordkeeping, traceability, conduct of potential post- marketing studies and post- marketing submission requirements, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP or equivalent requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, prior notification / review and / or approval of advertising and promotional materials by the competent authorities, record- keeping and GCP requirements for any clinical trials that we conduct post- approval. Even when marketing approval of a product or product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. When a product or product candidate receives marketing approval, the accompanying label may limit the approved use of the drug or the FDA or other regulatory authorities may require that contraindications, warnings or precautions, including in some cases, a boxed warning, be included in the product labelling or accompanying documentation, which could limit sales of the product. The FDA and other relevant regulatory authorities may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Failure to complete such post- marketing requirements in accordance with the timelines and conditions set forth by the FDA and other relevant regulatory authorities could significantly increase costs, result in regulatory enforcement, or delay, limit or ultimately restrict the commercialization of such product. The FDA and other relevant regulatory authorities closely regulate the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labelling and that promotional and advertising materials and communications are truthful and non- misleading. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, regulatory authorities impose stringent restrictions on manufacturers' communications and if we do not market our products or product candidates for their approved indications or in a manner which regulators believe to be truthful and non- misleading, we may be subject to enforcement action. Moreover, in the EU and the UK we will be prohibited from promoting prescription- only medicinal products to individuals who are not healthcare professionals. Violations of the FDCA in the ~~United States~~ **U. S.** and other comparable laws and regulations in other jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other comparable non- U. S. regulatory agencies alleging violations of ~~United States~~ **U. S.** federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in other jurisdictions. In addition, later discovery of previously unknown adverse events or other problems with our 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~~ **common Shares** ~~shares~~ and may yield various results, including: • restrictions on the manufacture of such products or product candidates; • restrictions on the labelling or marketing of such products or product candidates, including a "black box" warning or contraindication on the product label or communications containing warnings or other safety information about the product; • restrictions on product distribution or use;

• requirements to conduct post- marketing studies or clinical trials, or any regulatory holds on our clinical trials; • requirement of a REMS (or equivalent outside the ~~United States~~ **U. S.**); • Warning or Untitled Letters or similar communications from other relevant regulatory authorities; • withdrawal of the product or product candidates from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products or product candidates; • fines, restitution or disgorgement of profits or revenues; • suspension, variation, revocation or withdrawal of marketing approvals; • refusal to permit the import or export of our products or product candidates; **Table of Contents** • seizure of our products or product candidates; or • lawsuits, injunctions or the imposition of civil or criminal penalties. Non- compliance by us or any current or future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance can also result in significant financial penalties. Our failure to maintain or continuously improve our quality management program could have an adverse effect upon our business, subject us to regulatory actions and cause patients to lose confidence in us or our products, among other negative consequences. Quality management plays an essential role in the manufacturing of drugs or drug products, conducting clinical trials, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our products and product candidates. We seek to maintain a robust quality management program which includes the following broad pillars of quality: • monitoring and assuring regulatory compliance for clinical trials, manufacturing and testing of good applicable practice (“ GxP ”) (e. g., GCP, GLP and GMP regulated) products; • monitoring and providing oversight of all GxP suppliers (e. g., contract development manufacturing organizations and CROs); • establishing and maintaining an integrated, robust quality management system for clinical, manufacturing, supply chain and distribution operations; and • cultivating a proactive, preventative quality culture and employee and supplier training to ensure quality. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, monetary sanctions, injunctions to halt manufacture and distribution of drugs or drug products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal, suspension or variation of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, or a loss of patient confidence in us or our products or product candidates, which may result in difficulty in successfully launching products and the loss of potential future sales, which could have an adverse effect on our business, financial condition, and results of operations. Breakthrough Therapy Designation, Fast Track Designation, ~~Regenerative Medicine Advanced Therapy Designation~~ or Orphan Drug Designation by the FDA or other relevant regulatory authorities, even if granted for any product candidate, may not lead to a faster development, regulatory review or approval process, and does not necessarily increase the likelihood that any product candidate will receive marketing approval in the United States or other jurisdictions. We have sought, or may in the future seek, Breakthrough Therapy Designation, Fast Track ~~Designation, Regenerative Medicine Advanced Therapy~~ Designation or Orphan Drug Designation for certain of our product candidates. For example, in July 2021, Immunovant was granted orphan drug designation in the U. S. by the FDA for batoclimab for the treatment of MG and, in August 2022, it received orphan drug designation from the European Commission for batoclimab for the treatment of MG. Immunovant plans to seek orphan drug designation from the FDA for ~~batoclimab and /-or~~ **IMVT- 1402 and / or batoclimab** where there is a medically plausible basis for ~~batoclimab and /-or~~ **IMVT- 1402 and batoclimab**’ s use. Immunovant may also seek orphan drug designation for ~~batoclimab and /-or~~ **IMVT- 1402 and batoclimab** for the treatment of other indications in the E. U. We may also do so for other of our products and product candidates in the future where there is a basis for doing so. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed on potentially less efficacious control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a breakthrough therapy, the FDA may later decide that such product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. ~~Recently~~ **Table of Contents** ~~Recently~~, there has been heightened scrutiny of the accelerated approval pathway, with some stakeholders advocating for reform. The HHS Office of Inspector General has initiated, and partly completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Consolidated Appropriations Act, 2023, revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things, requires the FDA to specify the conditions for required post- marketing trials, permits the FDA to require such trials to be underway prior to, or within a specific period after, approval, requires sponsors to provide reports on post- marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed, makes the failure to conduct required post- marketing trials with due diligence and the failure to submit the required reports prohibited acts, and details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis. We understand that FDA approval letters to products granted accelerated approval subsequent to passage of this legislation are including language that informs the sponsor that they are required to submit status reports of the progress of each requirement no later than 180 days post- approval and every 180 days thereafter. **Further, we understand that a company received a Complete Response Letter for a product seeking accelerated approval in two indications because enrollment had not yet**

**begun for confirmatory portions of ongoing clinical trials.** 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~~ **U. S.** and the European Economic Area (the “ EEA ”), may designate drugs and biologics for relatively small patient populations as orphan drugs. In the ~~United States~~ **U. S.**, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200, 000 individuals annually in the ~~United States~~ **U. S.** or for which there is no reasonable expectation that costs of research and development of the drug for the disease or condition can be recovered by sales of the drug in the ~~United States~~ **U. S.** Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for the same orphan indication for that time period. In the ~~United States~~ **U. S.**, in order for a product to receive orphan drug exclusivity, FDA must not have previously approved a drug considered the same drug for the same orphan indication, or the subsequent drug must be shown to be clinically superior to such a previously approved same drug. The applicable period of marketing exclusivity is seven years in the ~~United States~~ **U. S.** A similar market exclusivity scheme exists in the EEA. The European Commission, on the basis of a scientific opinion by the EMA’ s Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition affecting not more than five in 10, 000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, Orphan Drug Designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Orphan designation in the EU entitles a party to certain benefits, such as scientific assistance (protocol assistance), financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This orphan market exclusivity period prevents the European Commission, EMA and the competent authorities of the EU Member States from accepting an application or granting marketing authorization for any similar medicinal product intended for the same orphan indication. The orphan market exclusivity applies in parallel to the “ normal ” data and market exclusivity in the EEA, whereby no company can make reference to (rely on) the innovator drug company’ s preclinical and clinical data in order to obtain a marketing authorization for eight years from the date of the first approval of the innovator drug in the EEA and no generic **or biosimilar** drug can be marketed for ten years from the first approval of the innovator drug in the EEA; the innovator drug may qualify for an extra year’ s protection. This additional one year of marketing exclusivity may be obtained where the innovator company is granted **, during the first eight years of the ten years market exclusivity,** a marketing authorization for a significant new indication for the relevant medicinal product. In such a situation, the generic **or biosimilar** company can only market their product after 11 years from the first grant of the innovator company’ s marketing authorization for the product in the EEA. ~~Orphan~~ **Table of ContentsOrphan** drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. In the EEA, orphan drug designation, and the related benefits, may be lost if it is established before the market authorization is granted that the designation criteria are no longer met. Moreover, the ten year orphan market exclusivity in the EEA may be reduced to six years if the orphan drug designation criteria are no longer met at the end of the fifth year since grant of the approval, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. ~~On~~ **In** April 26, 2023, as part of the EU Pharmaceutical Strategy, the European Commission published a proposal for a comprehensive revision of the EU pharmaceutical legislation (which will not apply in the UK). If adopted by the European Parliament and the Council, the new legislation is likely to significantly change the regulatory regime applicable to both the “ normal ” data and market exclusivity and the orphan exclusivities and reduce / modulate the exclusivities and rewards that could be granted to medicinal products. In addition, the proposal envisages changes to the concept of unmet medical need and considers introducing novel rewards for orphan medicinal products addressing a high unmet medical need. The adoption of the new legislation is not expected before **2024-2025** and it will start to apply 18 months after the entry in force. If we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or the European Commission can subsequently approve the same drug for a different condition or the same condition if the FDA or the EMA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EEA, a marketing authorization may also be granted, for the same therapeutic indication, to a competitor with a similar medicinal product during the exclusivity period if we are unable to supply sufficient quantities of the medicinal product for which we received marketing authorization. Moreover, our orphan exclusivity may be reduced if we are unable to comply with any new obligation that may be imposed by the upcoming reform of the EU pharmaceutical legislation, as discussed above. Moreover, a September 2021 Eleventh Circuit decision in Catalyst

Pharmaceuticals, Inc. vs. Becerra regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug's orphan designation could significantly broaden the scope of orphan drug exclusivity for such products. In January 2023, the FDA, however, issued a Federal Register notice clarifying its approach to orphan drug exclusivity following the Catalyst decision. Consistent with the court's decision, the FDA set aside its approval of the drug at issue in the case, but announced that, while complying with the court's order in Catalyst, the FDA intended to continue to apply its regulations tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order. Legislation has also been introduced that may reverse the Catalyst decision. Receipt of marketing approval for our products and product candidates does not guarantee that they will achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. The commercial success of our products and product candidates will depend upon their degree of market acceptance by physicians, patients, third- party payors and others in the medical community. Receipt of marketing approval for our products and product candidates does not guarantee that they will gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance for any product or product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and safety of such products and product candidates as demonstrated in pivotal clinical trials and published in peer- reviewed journals; • the potential and perceived advantages compared to alternative treatments, including any similar generic treatments; • the ability to offer these products for sale at competitive prices; • the ability to offer appropriate patient financial assistance programs, such as commercial insurance co- pay assistance; • convenience and ease of dosing and administration compared to alternative treatments; • the clinical indications for which the product or product candidate is approved by FDA or comparable non- U. S. regulatory agencies; **Table of Contents** • product labelling or product insert requirements of the FDA or other comparable non- U. S. regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labelling; • restrictions on how the product is dispensed or distributed; • the timing of market introduction of competitive products; • publicity concerning these products or competing products and treatments; • the strength of marketing and distribution support; • favorable third- party coverage and sufficient reimbursement; and • the prevalence and severity of any side effects or adverse events. Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe such products. If approved, our product candidates regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the " Affordable Care Act " or " ACA "), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the " BPCIA "), which created an abbreviated approval pathway under section 351 (k) of the PHSA for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, a section 351 (k) application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product submitted under section 351 (a) of the PHSA containing the competing sponsor's own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA and the FDA only approved the first interchangeable biosimilar in July 2021. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples legislation, purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower- cost generic and biosimilar versions of those drugs and biological products, including by allowing generic drug, 505 (b) (2) NDA or biosimilar developers to obtain access to branded drug and biological product samples. Its provisions do have the potential to facilitate the development and future approval of biosimilar versions of our products, introducing biosimilar competition that could have a material adverse impact on our business, financial condition and results of operations. Whether approval of a biological product qualifies for reference product exclusivity turns on whether the FDA consider the approval a " first licensure. " Not every licensure of a biological product is considered a " first licensure " that gives rise to its own exclusivity period. We believe that our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise. The extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is variable, and will depend on a number of marketplace and regulatory factors. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. **If we Our commercialization efforts are dependent on** ~~unable to continue to expand~~ our sales, marketing and distribution capabilities, **, including** ~~or enter into~~ agreements with third parties to sell, market and distribute our products and product candidates, ~~we may not be successful in commercializing those products and, if approved, product candidates.~~ We are currently in the process of further building out our commercial sales organization for the sales, marketing and distribution of VTAMA, which was approved by the FDA in May 2022 for the treatment of plaque psoriasis in adults in the U. S. The costs of establishing and maintaining this infrastructure may exceed the cost- effectiveness of doing so. In order to effectively market our products and, ~~if approved, product candidates, we must~~ **successfully employ** ~~continue to expand~~ our sales, distribution, marketing, ~~compliance, managerial~~ and

related other non-technical capabilities or make arrangements with third parties to perform these services. To achieve our subsidiary Dermavant has established a commercial success sales organization for the sales of our products and, if 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. Other Vants with product candidates in late-stage clinical development, we will need an effective including Immunovant, do not currently have a sales and marketing organization or distribution infrastructure, and would expect to outsource these build a sales, marketing and distribution functions—function 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—make arrangements with third parties to perform these services engage in commercialization activities with respect to our products or product candidates. There are risks involved with both establishing our own and maintaining internal commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product 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. **At Dermavant, the costs of maintaining this sales, marketing and distribution infrastructure may exceed the net revenues we are able to generate from the sale of VTAMA.** 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 may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring a product 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: **Table of Contents** • 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 \$ ~~11-13, 803-508~~ to \$ ~~23-27, 607-018~~ for each false claim or statement for penalties assessed after ~~December 13 January 30, 2021-2023~~, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs; • the federal health care fraud statute (established by Health Insurance Portability and Accountability Act of 1996 (“HIPAA ”)), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH ”), and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses and most healthcare providers (collectively, “covered entities ”), and such covered entities’ “business associates,” defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of the covered entity; • various privacy, cybersecurity and data protection laws, rules and regulations at the international, federal, state and local level, **which** impose obligations with respect to safeguarding the privacy, security, and cross- border transmission of personally identifiable data, including personal health information; • the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti- Kickback Statute; or (4) failing to report and return a known overpayment; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’ s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value ” made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value ” to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); **and** **andTable of Contents** • analogous state and EU and foreign national laws and regulations, such as state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and several recently passed state laws that require disclosures related to state agencies and / or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes, some of which contain ambiguous requirements that government officials have not yet clarified; and EU and foreign national laws prohibiting promotion of prescription- only medicinal products to individuals other than healthcare professionals, governing strictly all aspects of interactions with healthcare professionals and healthcare organizations, including prior notification, review and / or approval of agreements with healthcare professionals, and requiring public disclosure of transfers of value made to a broad range of stakeholders, including healthcare professionals, healthcare organizations, medical students, physicians associations, patient organizations and editors of specialized press. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other applicable health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena, civil investigative demand or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and our results of operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Healthcare legislative and regulatory measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations. The ~~United States~~ **U. S.** and many

other jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities for our products and affect our ability to profitably sell our products, and prevent or delay marketing approval of our current and any future product candidates. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labelling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States U. S., there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs for pharmaceuticals. For example, as discussed in March 2010-detail above, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U. S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. However, effective January 1, 2025, this program will be replaced as a part of the Part D benefit redesign enacted under the IRA. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, with unpredictable and uncertain results. During previous Congressional sessions, Congress had introduced several pieces of legislation aimed at significantly revising or repealing the ACA and may in the future consider legislation to replace, modify or augment elements of the ACA. In addition, other legislative changes have been proposed and adopted in the United States U. S. since the ACA was enacted. In particular August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through the first six months of 2023 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. There was a 1% reduction through the end of June 2022, after which the cuts returned to 2%. Absent further Congressional action, there is a possibility that an up to 4% Medicare sequester could be triggered in January 2023, pursuant to the Statutory Pay-As-You-Go Act of 2010 ("PAYGO"). Under PAYGO, if the five- or ten- year PAYGO scorecard shows a net cost at the end of a Congressional session, then the Office of Management and Budget is required to issue a sequestration order. The American Rescue Plan Act of 2021 was expected to trigger a PAYGO sequestration order at the end of the 2021 Congressional session. However, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024. There has been increasing legislative and enforcement interest in the United States U. S. 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 Most of prescription notably and as described in detail above, the IRA brought about sweeping changes to the payment for drugs under Medicare, and reform government program reimbursement methodologies for drugs. In July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates, and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. Moreover, in August 2022, Congress enacted the IRA, a law with sweeping changes to the payment of drugs under the Medicare program. Among other provisions, There are several ongoing legal challenges to the IRA 's contains (i) a drug price negotiation program, and we cannot predict the outcome of these cases or the impact they could have on implementation of the law. Over time, the IRA could increase our government discount and rebate liabilities, reduce the revenues we are able to collect from sales of our products as well as present challenges for certain high spend Medicare drugs payor negotiations and formulary access. However, the degree of impact that the IRA will ultimately have upon our business remains unclear at this been on the market for a certain length of time. Table of Contents Moreover, individual states in the U. S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including lack generic or biosimilar competition under which Medicare prices for such drugs are capped by a "maximum fair price or patient reimbursement constraints, discounts, restrictions"; (ii) new manufacturer rebate obligations on certain drugs paid under Medicare Part B or D whose product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing, such as in Colorado and Florida, as discussed in detail above. Legally mandated prices- price controls on payment amounts by third increase faster than inflation relative to a benchmark period; and (iii) a redesign of the Part D benefit, including capping patients' annual out- party payors or other restrictions could harm our business, results of -pocket costs-operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on Part D drugs, lowering the beneficiary out-of-pocket threshold, streamlining the Part D benefit to eliminate the "coverage gap" phase, and replacing the manufacturer coverage gap discount program with a new manufacturer discount program that provides discounts

throughout the post-deductible benefit phases. It is possible that Congress or **our product pricing** the Administration may take further actions to control drug prices. In October 14, 2022, President Biden issued an executive order calling on the Secretary to consider whether to select for testing by the CMS innovation center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. We cannot predict how these new provisions would be implemented or their impact on Roivant. Additionally, U. S. regulators continue to pursue policies designed to lower drug costs for federal programs and patients. In May 2019, the CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. This rulemaking also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. However, Congress has adopted various delays on the implementation or enforcement of the rule, including a postponement until January 2032 under the IRA. On December 31, 2020, CMS enacted a final rule **expanding that, among other things, expanded** the scope of drug products that may be considered “line extensions” subject to inflationary rebates under the Medicaid Drug Rebate Program. **On May 23, 2023, CMS issued a Medicaid Drug Rebate Program proposed rule, which if finalized, would, among other things, require drug manufacturers to aggregate certain price concessions when calculating Best Price, establish a price verification survey, and amend the definitions of a “covered outpatient drug” and a “manufacturer.” These changes, if finalized, could deepen rebates owed on Medicaid utilization, expand the scope of products subject to Medicaid rebates, and subject manufacturer drug pricing practices to further scrutiny.** Moreover, upcoming legislative and policy changes in the EU and the UK, some of which may materialize in the near term, are aimed at increasing accessibility and affordability of medicinal products, as well as at increased cooperation between the EU Member States. Such initiatives may further impact the price and reimbursement status of our products in the future. There have been, and likely will continue to be, legislative and regulatory proposals at the national and state levels in jurisdictions around the world directed at containing or lowering the cost of healthcare, including prescription drugs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability **through product revenue**, 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 **sustained 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 **sustained** 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 Table of ContentsMarket** 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 U. S.**, no uniform policy of coverage and reimbursement exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product or, if approved, product candidate will be made on a plan-by-plan basis. For example, while we have previously disclosed successes in achieving payor coverage for VTAMA, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product, **and payors may periodically review and change their coverage and reimbursement rates for products**. Discussions with payors, including PBMs, related to VTAMA are ongoing and **whether such payors will provide coverage for VTAMA may change over** and if so to what extent, is uncertain at this time. Additionally, a third-party payor’s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position



of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product or, if approved, product candidates, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the product or product candidate. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products or, if approved, product candidates, to the extent that patients who are prescribed our products or, if approved, product candidates, are not separately reimbursed for the cost of the product. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product or, if approved, product candidate. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product or, if approved, product candidate that we develop. Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the ~~United States~~ **U. S.** 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~~ **U. S.** and in other countries where our products and, if approved, product candidates, are sold will not harm our ability to profitably sell our products and, if approved, product candidates. In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products or, if approved, product candidates. In addition to continuing pressure on prices and cost containment measures, legislative developments in the EU or the EU Member States may harm our ability to profitably sell our products and, if approved, product candidates. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national EU Member States law. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. The healthcare budgetary constraints in most countries have resulted in restrictions on the pricing and reimbursement of medicines, and a similar approach is taken in the UK where a key consideration is the affordability of drugs for treatment of patients under the National Health Service. **In the UK there is also a budget cap on branded health service medicines, and a new voluntary pricing scheme has been introduced that increases the level of rebate payment that a company is required to make to the National Health Service to take account of any spend on branded products that is above the agreed cap, and also imposes different payment rates for newer or older medicines. A consultation on the parallel statutory scheme, which applies to companies that are not members of the voluntary scheme, is ongoing, but is also likely to lead to higher rebates than previously. In** markets outside of the ~~United States~~ **U. S.**, EU and UK, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. All of this could affect our ability to commercialize our products and, if approved, product candidates. **Recent Table of Contents** 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~~ **U. S.** 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~~ **U. S.**, the Medicare Modernization Act (“MMA”) contains provisions that may change U. S. importation laws and expand pharmacists’ and wholesalers’ ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U. S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public’s health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, on November 23, 2020, several industry groups filed federal lawsuits in the U. S. District Court for the District of Columbia, requesting injunctive relief to prevent implementation of the rule. The court dismissed the case in February 2023. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for “best price” or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code (“NDC”), for an FDA-approved

drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. In addition, the July 2021 executive order pertaining to drug pricing directs the FDA to support and work with States and Indian Tribes to develop importation plans to import prescription drugs from Canada under the MMA and final rule. **Several states have enacted laws intended to support importation processes and have submitted importation program proposals to FDA. On January 5, 2024, FDA authorized Florida's importation program for the importation of certain prescription drugs from Canada into Florida; however, the state must file Pre-Import Requests for specific drug products that FDA must grant before any importation may take place. In response, Health Canada issued a statement on January 8, 2024 making clear that it is ready to take immediate action to help safeguard the Canadian drug supply if necessary.** If implemented **in Florida or elsewhere**, importation of drugs from Canada may materially and adversely affect the price we receive for our 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 **other** legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for our products and, if approved, product candidates and adversely affect our future revenues and prospects for profitability.

**Other Risks Related to Our Business and Industry** We depend on the knowledge and skills of our senior leaders and may not be able to manage our business effectively if we are unable to attract and retain key personnel. We have benefited substantially from the leadership, performance and vision of our senior leaders, including our Principal Executive Officer, Matthew Gline, as well as other senior executives at Roivant and the Vants. We rely greatly on the investment experience and medical and scientific expertise of our senior leadership team to identify product candidates and guide future investments and opportunities, as well as the drug development expertise of our and the Vants' senior leadership to guide the preclinical and clinical development of our product candidates. Our success will depend on our ability to retain our current management team. In addition, while we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties related to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. Competition for senior leadership in the healthcare investment industry is intense, and we cannot guarantee that we will be able to retain our key personnel or that of our Vants. **Our Table of Contents** Our senior leaders and key employees may terminate their positions with us at any time. Due to the small number of employees at some of the Vants, the loss of a key employee may have a larger impact on our business. In particular, we rely on a limited number of employees in certain key jurisdictions, including the **United Kingdom (the "U. K.")** and Switzerland. If we lose one or more members of our or the Vants' senior leadership teams or other key employees, our ability to successfully implement our business strategies could be adversely impacted. Replacing these individuals may be difficult, cause disruption and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain "key person" insurance for any members of our senior leadership team or other employees. To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided certain equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our share price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain invaluable employees, members of our management, scientific and development teams may terminate their employment with us at any time. Although we have employment agreements with our key employees, certain of these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt operations. In connection with our continued growth, we expect to hire, either directly or through our current or future affiliates, additional employees for our managerial, finance and accounting, clinical, scientific and engineering, regulatory, operational, manufacturing, sales and marketing teams. We may have difficulties in connection with identifying, hiring, integrating and retaining new personnel. Future growth would impose significant additional responsibilities on management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of operations across our entities, which may result in weaknesses in infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and ability to commercialize product candidates and new technologies and compete effectively will partly depend on our ability to effectively manage any future growth. Many of the other pharmaceutical and healthcare technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than us. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop our products and product candidates will be harmed, which could negatively impact our financial condition, results of operations and cash flows. Our international operations may expose us to business, legal, regulatory, political, operational, financial and economic risks

associated with conducting business globally. Part of our business strategy involves potential expansion internationally with third-party collaborators to seek regulatory approval for our products and product candidates globally. Doing business internationally involves a number of risks, including but not limited to: • multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our products or, if approved, product candidates, in various countries; • difficulties in managing operations in different jurisdictions; **Table of Contents** • 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 U. S.**, Foreign Corrupt Practices Act (the “FCPA”), including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010 (the “U. K. Bribery Act”), and similar anti-bribery and anti-corruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors’ activities. Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our financial condition, results of operations and cash flows. Unfavorable global and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations. Our business could be adversely affected by global or regional economic, political and health conditions. For example, various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), **international hostilities (including the current military conflict between Russia and Ukraine and the conflict in the Middle East)**, trade disputes between nations and the current and future conditions in the global financial markets. For example, if sustained high rates of inflation or other factors were to significantly increase our business costs, we may be unable to manage such increased expenses or pass through price increases. A global financial crisis or global or regional political and economic instability, wars, terrorism, civil unrest, outbreaks of disease (for example, COVID-19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility in the capital and credit markets and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility, and conduct of our clinical trials, as well as temporary closures of the facilities of suppliers or contract manufacturers in the biotechnology supply chain. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and / or medications, which could have a negative impact on our commercial sales - **The COVID-19 outbreak, including developments involving subsequent COVID-19 variants, significantly affected the financial markets of many countries and resulted and may in the future result in a variety of federal, state and local orders, guidance and restrictions. We cannot, at this time, predict the continued impact that the COVID-19 pandemic will have on our ongoing and planned clinical trials and other business operations, including our commercialization activities.** A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business. We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve certain regulatory approvals before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize our products and, if approved, product candidates and ultimately harm our financial condition. The development and commercialization of new drug products is highly competitive. Now and in the future we may face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our products and product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development and commercialization of products and product candidates for the treatment of the indications that we are also pursuing. Examples of such competing products include, but are not limited to: • ZORYVE (roflumilast), a topical PDE4 inhibitor, a potential competitor to VTAMA; • OPZELURA (ruxolitinib), a topical Janus kinase inhibitor, a potential competitor to VTAMA; • **PRA023, an TL1A antibody, a potential competitor to RVT-3101**; • VYVGART (efgartigimod alfa-fc) **and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)**, a neonatal Fc receptor blocker **blockers**, a potential competitor **competitors** to batoclimab and IMVT-1402 **and batoclimab**; **Table of Contents** • Nipocalimab and **RYSTIGGO (rozanolixizumab - noli)**, anti-FcRn antibodies, potential competitors to batoclimab **and IMVT-1402 and batoclimab**; • TEPEZZA (teprotumumab-trbw), an insulin-like growth factor-1 receptor inhibitor, a potential competitor to batoclimab; and • **SOTYKTU-Dazukibart, an interferon beta (deucravacitinib-IFN-beta)**, a TYK2 inhibitor, a potential competitor to brepocitinib. Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our

competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than our products and product candidates. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our products and product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our products or product candidates uneconomical or obsolete and we may not be successful in marketing our products or, if approved, any product candidates we may develop against competitors. In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and / or enforceability of our patents relating to our competitors' products and our competitors may allege that our products or product candidates infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for our products and, if approved, any product candidates we may develop. The markets in which our healthcare technology Vants participate are competitive, and if we do not compete effectively, our business and operating results could be adversely affected. The overall market for healthcare technologies and software is global, rapidly evolving, competitive and subject to changing technology and shifting customer focus. Our healthcare technology Vants, including Lokavant, a clinical trial technology company, and VantAI, which uses machine learning to build computational models to generate new molecular entities for targets of interest, face competition from well- established providers of similar solutions, certain of which may have long- standing relationships with many of our current and potential customers, including large biopharmaceutical companies. We also face competition from solutions that biopharmaceutical companies develop internally and from smaller companies that offer products and services directed at more specific markets than we target, enabling these smaller competitors to focus a greater proportion of their efforts and resources on these markets, as well as a large number of companies that have been founded with the goal of applying machine learning technologies to drug discovery. Many of our competitors are able to devote greater resources to the development, promotion, and sale of their software solutions and services. Third parties with greater available resources and the ability to initiate or withstand substantial price competition could acquire our current or potential competitors. Our competitors may also establish cooperative relationships among themselves or with third parties that may further enhance their product offerings or resources. If our competitors' products, services or technologies become more accepted than our solutions, if our competitors are successful in bringing their products or services to market earlier than ours, if our competitors are able to respond more quickly and effectively to new or changing opportunities, technologies, or customer requirements, or if their products or services are more technologically capable than ours, then the business and prospects of these Vants could be adversely affected. In addition, we are facing increasing competition from other companies that are utilizing artificial intelligence (" AI ") and other computational approaches for drug discovery. Some of these competitors are involved in drug discovery themselves and / or with partners, and others develop software or other tools utilizing AI which can be used, directly or indirectly, in drug discovery. To the extent these other AI approaches to drug discovery prove to be more successful than our approaches, we may not be successful in identifying potential targets or attracting collaborators to work with us. **We Table of Contents 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 Common Shares 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 common Shares shares** to decline. We may not hold a controlling stake in certain of our Vant affiliates and thus may not be able to direct our business or the development of our product candidates. In certain of our Vants, we may hold less than a majority ownership interest or otherwise be limited in our ability to direct or control the business and the development of the product candidates or technologies at the Vant. In addition, for certain other Vants, including Immunovant, we may in the future come to hold less than a majority ownership interest in the Vant. Furthermore, even if we own a majority ownership interest in a Vant, we may not necessarily be able to control the outcome of certain corporate actions. If the business or development of a product candidate at one of these Vants were to face challenges, we would be adversely affected as a result and would be limited in our ability to cause or influence the Vant in question to take appropriate remediative actions. Our business and operations would suffer in the

event of system failures, cyber- attacks or a deficiency in our cyber- security protections. Our computer systems, as well as those of various third parties on which we presently rely, or may rely on in the future, including our CROs and other contractors, consultants, and law and accounting firms, may sustain damage from or otherwise be subject to computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security breaches from inadvertent or intentional actions by our employees, third- party vendors, contractors, consultants, business partners, and / or other third parties. Any of the foregoing may compromise our system infrastructure, or that of our third- party vendors and other contractors and consultants, or lead to data leakage. The risks of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by traditional computer “ hackers, ” threat actors, personnel (such as through theft or misuse), sophisticated nation- state and nation- state- supported actors, sovereign governments and cyber terrorists, have generally increased over time, including for geopolitical reasons and in conjunction with military conflicts and defense activities, along with the number, intensity and sophistication of attempted attacks and intrusions from around the world. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber- attacks that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our products and product candidates. Currently and in the coming years, there may be an increased risk of cybersecurity attacks due to the **ongoing Russian- Russia- invasion of Ukraine conflict**, including cybersecurity attacks perpetrated by Russia or others at its direction in response to economic sanctions and other actions taken against Russia as a result of the invasion. Any increase in such attacks on us or our third- party vendors or other systems could adversely affect our network systems or other operations. **We Table of Contents We** generally require our third- party providers to implement effective security measures and to identify and correct for any information technology security failures, deficiencies or breaches. Although we seek to supervise such third parties’ security measures, our ability to do so is limited. If the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such incidents and to develop and implement protections to prevent future events of this nature from occurring. We cannot anticipate all possible types of security threats and we cannot guarantee that our data protection efforts and our investments in information technology will prevent significant breakdowns, data leakages, security breaches in our systems, or those of our third- party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If a significant cybersecurity compromise were to occur, it could result in a material disruption of our commercialization efforts, drug development programs, and other business operations. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we rely on third parties to supply components for and to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or in an **inappropriate unauthorized** 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**. **The actual or perceived failure by us, our customers, partners or vendors to comply with** such laws, regulations, policies and contractual obligations could **result in harm to our reputation, regulatory investigations or actions, significant fines and liability, disruption of our clinical trials or other material adversely- adverse affect effects to** our business. **Certain of our subsidiaries and affiliates collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials in the U. S. and abroad necessary to operate their businesses and for legal, marketing and other business- related purposes**. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally- identifying information, which among other things, impose requirements relating to the privacy, security, transmission and disposal of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide. **Any Failure- failure by us, or our subsidiaries or affiliates,** to comply with applicable privacy and data security laws and regulations could result in enforcement actions against us, including possible fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. There are numerous U. S. federal and state laws and regulations related to the privacy, data protection and security of personal information. At the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards for “ covered entities ” (group health plans and most healthcare providers) that limit the use and disclosure of individually identifiable health information those entities **and their service providers** receive or create (“ protected health information ”), and require the implementation of administrative, physical and technological safeguards to protect the security, confidentiality, integrity and availability of electronic protected health information. While we generally are not subject to the HIPAA privacy or security regulations, we do business with various entities **that are subject those HIPAA regulations** (including clinical trial investigators) **that are subject those regulations**, and we have to expend resources to understand their obligations, adjust contractual **relationships terms** in light of those obligations, or otherwise modify our business practices. Congress **has is actively considered- considering expanding- adopting legislation to regulate** the scope **collection, use, and disclosure** of **personal health information more broadly than** the HIPAA privacy and security regulations. **Such legislation might** and we

may in the future ourselves become subject to them or similar regulations, which would require us to make additional substantial expenditures and would likely create additional liability risks. In The Federal Trade Commission (“FTC”) Act, while not focused on data privacy or security, has proven to be a significant federal enforcement tool with respect to protection of personal information, and recently, personal health information in particular. The FTC has used its authority under Section 5 of the FTC Act, which prohibits unfair and deceptive practices affecting consumers, to bring numerous cases against companies for failing to protect the privacy or security of personal information in a manner that is reasonable and fully consistent with stated privacy policies, notices, or other representations. Particularly because the FTC has taken these actions based on theories that are not codified in regulations, the optimal means to mitigate the risk of such an action are uncertain. Table of Contents

In addition, many an increasing number of 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 complicates compliance efforts. For example, the California Confidentiality of Medical Information Act (the “CMIA”), a statute that similar to the HHPAA privacy and security regulations, expressly applies to pharmaceutical companies (as well as companies that provide certain technologies for processing personal health information), and imposes stringent data privacy and security requirements and obligations with respect to the personal health information of California residents. Among other things, the CMIA, with limited exceptions, requires that a pharmaceutical company obtain a signed, written authorization from a patient or company employee in order to disclose his or her personal health information and requires pharmaceutical companies to maintain reasonable security measures to protect such information. The CMIA authorizes administrative fines and civil penalties of up to \$ 25, 000 for willful violations and up to \$ 250, 000 if the violation is for purposes of financial gain, as well as criminal fines. Washington State’s My Health My Data Act, and a similar Nevada law, both of which became effective on March 31, 2024, generally require consent for the collection and use of personal health information, and a separate consent for sharing any such information, and create additional risk for our collection of health information. Violations of the Washington State law can result in civil penalties of up to \$ 7, 500 per violation, up to \$ 25, 000 in treble damages at the sole discretion of the court, and injunctive relief. Consumers also may bring their own actions to recover (i) actual damages, (ii) treble damages; and (iii) attorney’s fees. Violations of the Nevada law can result in up to \$ 10, 000 civil penalties per violation and injunctive relief. In addition, another more approximately 15 states have enacted broadly applicable California consumer privacy law laws, which apply not only to personal health information but also many other forms of information. These laws, including the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, the “CCPA”), typically which was substantially amended in 2020 pursuant to the California Privacy Rights Act (the “CPRA”) generally requires - require us to provide notice to California state residents regarding our collection, use, and sharing of the their personal information we collect, use and give state share and to honor such residents’ privacy rights, including the right to opt- out of the sale or sharing for targeted advertising of their personal information. The CCPA provides for civil penalties for violations, as well as the right to limit our use and disclosure of their “sensitive” (including health) personal information. Some of these laws require that we obtain signed consent in order to collect, use or share any sensitive personal information. Most of these laws are enforceable only by state authorities, but the CCPA provides a private right of action for data security breaches that result in the compromise of highly sensitive personal information, which may increase the likelihood of, and risks associated with, data breach litigation. Both the California Attorney General and an agency established pursuant to the CPRA amendments, the California Privacy Protection Agency, have authority to implement and enforce the CCPA. California’s aggressive steps to protect consumer privacy have been followed by similar actions in the legislatures of other states, including Virginia, Colorado, Utah, Connecticut, Iowa, Indiana, Montana and Tennessee, all of which have passed CCPA / CPRA - like legislation to provide their respective residents with similar rights. Recently, Washington State enacted a broadly applicable law to protect the privacy of personal health information specifically, the “My Health, My Data Act,” which generally requires consent for the collection, use, or sharing of any such information. 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 U. S., laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in EEA, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the “GDPR”). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on controllers, including inter alia: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with data protection rights of data subjects; and (iv) reporting of certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible). The GDPR also prohibits the transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. The EU- US Privacy Shield was such a transfer mechanism put in place by the EU and the United States U. S., but the Privacy Shield was invalidated for international transfers of personal data in July

2020 by the Court of Justice of the European Union (“ CJEU ”). A replacement of the Privacy Shield is currently being – the **EU- U. S. Data Privacy Framework (“ DPF ”)** was since developed. **In July** On December 13, 2022-2023, following the signature of a U. S. Executive Order by President Biden on October 7, 2022, the European Commission issued a draft adequacy decision which, if adopted and **EU implemented** not successfully challenged in court, is intended to address the concerns expressed by CJEU in their-- **the 2016 ruling and allow DPF. Companies can now use this new mechanism to** transfer of personal data from the **EEA EU** to companies in the U. S. which **commit and potentially from Switzerland** to **comply with the U. S., subject to national implementation in Switzerland. The UK Extension to** the EU- U. S. Data Privacy Framework (“ **Data Bridge ”)** entered into force on **October 12, allowing certifying entities to transfer personal data from the UK to the U. S.** At the moment, it is unclear if the adequacy decision will be adopted at EU level and whether the anticipated legal challenges against **this decision the DPF**, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful. **While in July** In a related vote on May 11, 2023-2020, the **European Parliament adopted a resolution calling on the European Commission not to adopt the adequacy decision in its present form but to continue negotiations with the U. S. to ensure that the new framework addresses the concerns expressed by the CJEU. The European Parliament’s resolution is not binding on the Commission but it will be taken into account by the Commission when considering its adequacy decision. The CJEU upheld the validity of standard contractual clauses (“ SCCs ”) as a legal mechanism to transfer personal data but to jurisdictions that the European Commission has not found to provide an adequate level of protection and while the European Commission adopted new SCCs in July 2021,** companies relying on SCCs **will must**, subject to additional guidance from regulators in the EEA and the U. K., **regularly need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. The use of** 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 EEA** privacy, data protection, and information security laws. Given that, at present, there are few, if any, viable alternatives to the SCCs **and the DPF**, any transfers by us or our vendors of personal information from **Europe the EEA to the US** may not comply with **European the EEA** data protection **law-laws**, which may increase our exposure to the GDPR’s heightened sanctions for violations of its cross- border data transfer restrictions and may prohibit our transfer of **EEA E-U** personal information outside of the **EEA E-U** (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products. **Moreover, the Table of Contents** 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 U. K.** and the EU (i. e., following the **United Kingdom U. K.**’ s exit from the EU — otherwise known as Brexit), data processing in the **United Kingdom U. K.** is governed by a **United Kingdom U. K.** version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the **United Kingdom U. K.**, on June 28, 2021 the European Commission issued an adequacy decision in respect of the **United Kingdom U. K.**’ s data protection framework, enabling data transfers from EU member states to the **United Kingdom U. K.** to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, this adequacy decisions will automatically expire in June 2025 unless the European Commission renews or extends it and may be modified or unilaterally revoked in the interim at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. Moreover, other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data. **In March 2024, the British Government published the Data Protection and Digital Information (No. 2) Bill intended to create a more business- friendly regime in the UK through changes to the existing legislation. At this stage it is unclear whether and when this legislation will be adopted and whether such legislative reforms could potentially lead the European Commission not to extend or to revoke the UK adequacy decision.** If we or our third- party service providers are unable to properly protect the privacy and security of personal information, or other **sensitive confidential** data we process in our business, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties. Enforcement activity from state Attorneys General and agencies such as the California Privacy Protection Agency, the **FTC 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 U. S., the threat of class action lawsuits based on data security breaches or alleged unfair practices adds a further layer of risk. We cannot be sure how these privacy laws and regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Data privacy remains an evolving landscape at both the domestic and international level, with new laws and regulations frequently being adopted and coming into effect. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our current practices. Significant resources are needed to understand and comply with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties, including 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 labelling, marketing or promotional restrictions; • decreased demand for our VTAMA, and current or future product candidates, if approved; and • loss of revenue. The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and



in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have acquired insurance coverage which extends to liabilities arising from the sale of our products; however, there is no assurance that we will be able to maintain this insurance coverage on commercially reasonable terms or in adequate amounts or that this coverage will be sufficient to cover any losses arising from any claims related to our products or, if approved, product candidates. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business, including preventing or limiting the commercialization of our products and, if approved, product candidates. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Certain of our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We or the third parties upon whom we depend may be adversely affected by earthquakes, outbreak of disease or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our offices, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our limited earthquake and flood insurance coverage, could have a material adverse effect on our business. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our research, products, product candidates, investigational medicines and the diseases our products, product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, our employees, affiliates and / or business partners may use social media for their personal use, and their activities on social media or in other forums could result in adverse publicity for us. Any negative publicity as a result of social media posts, whether or not such claims are accurate, could adversely impact us. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business. The use of social media also creates additional risks in the EEA and the UK where promotion of prescription-only medicines to patients and the general public is strictly prohibited. Social media content that is generated, shared or liked by our company or our directors, employees, staff or other representatives may potentially be perceived or construed as constituting prohibited promotion of prescription-only medicinal products and trigger enforcement and penalties. This is an area of increased scrutiny in both the EEA and the UK. **The United Kingdom's withdrawal from the European Union may Table of ContentsThe use of AI could expose us to liability or adversely impact affect our business. Certain ability to obtain regulatory approvals of our products-early-stage discovery Vants and healthcare technology businesses product candidates in the European Union and may require us use machine learning to incur additional expenses in order to develop, manufacture and AI as part of commercialize our products and product candidates in the their business European Union. We However, there are significant risks involved centrally managed and controlled in utilizing AI 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 **no assurance can be provided** that **our use** the transition period has concluded, applied provisionally from January 1, 2021 and formally entered into force on May 1, 2021. Further, in February 2023, an agreement in principle was reached by the UK and EU, known as the Windsor Agreement, relating to post-Brexit trade issues in Northern Ireland, which if implemented into the respective legislation, seeks to simplify the supply of AI medicines between Great Britain and Northern Ireland and will

**enhance** mean the EU legislation may not apply in all cases in Northern Ireland. There continues to be considerable uncertainty resulting from a lack of precedent and the complexity of the United Kingdom and the EU's intertwined legal regimes as to how Brexit (following the Transition Period) will impact the life sciences industry in the UK and Europe, including our company, including with respect to ongoing or **our business or operations or result in our business or operations being more efficient or profitable** 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 **AI algorithms may be flawed, insufficient, of poor quality, reflect unwanted forms of bias, or contain the other** Transition Period errors or inadequacies, Great Britain is any of which may no longer covered **be easily detectable; AI has been known to produce false or "hallucinatory" inferences or outputs; AI can present ethical issues and may subject us to new or heightened legal, regulatory, ethical or other challenges; and inappropriate or controversial data practices by developers and end** the centralized procedures for obtaining EU users, wide marketing authorizations and our **or** products will therefore require a separate marketing authorization to allow **other factors adversely affecting public opinion of AI, could impair the acceptance of AI solutions, including those incorporated in our businesses. If the AI solutions that we create or use are deficient, inaccurate or controversial, we could suffer from competitive harm, legal liability,** to market such products in Great Britain. The EU Clinical Trials Regulations which govern the conduct of clinical trials in the E. U. entered into application in January 2022 and **brand** consequently **or reputational harm, or other adverse impacts on our business and financial results. If we do not apply in** have sufficient rights to use the data or the other material or content on which our AI solutions or other AI tools we use **rely, we also may incur liability through the violation of applicable laws, third-party intellectual property, privacy or other rights, or contracts to which we are a party. In addition, regulation of AI is rapidly evolving worldwide as legislators and regulators are increasingly focused on these powerful emerging technologies. The technologies underlying AI and its uses are subject to a variety of laws, including intellectual property, privacy, data protection and cybersecurity, consumer protection, competition, and equal opportunity laws, and are expected to be subject to increased regulation and new laws or new applications of existing laws. AI is the subject of ongoing review by various U. K-S. It is unclear as to whether governmental and regulatory agencies, and various U. S. states and the other foreign jurisdictions relevant authorities in the EU and the United Kingdom are adequately prepared applying, or are considering applying, their platform moderation, cybersecurity, and data protection laws to AI or are considering general legal frameworks for AI** the additional administrative burden caused by Brexit. Any delay in obtaining, or an inability to obtain, any marketing approvals or necessary modifications to such approvals, as a result of Brexit or otherwise, would prevent us from or delay us commercializing our products and, if approved, product candidates in the United Kingdom and / or the EEA and restrict our ability to generate revenue and achieve and sustain profitability. In the short term, following the expiry of the Transition Period there 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. There are also differences between the regulatory regimes. For example, orphan designation in the United Kingdom (or Great Britain, depending on whether there is a prior centralized marketing authorization in the EEA) following Brexit is based on the prevalence of the condition in Great Britain as opposed to the 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. Further, there is no designation step required in the UK, and the criteria for orphan designation will be determined at the time of authorization. Given these uncertainties, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or EEA for our products and product candidates, which could significantly and materially harm our business. There is a degree of uncertainty regarding the overall impact that Brexit will have on (i) the marketing of pharmaceutical products, (ii) the process to obtain regulatory approval in the United Kingdom or Great Britain for product candidates or (iii) the award of exclusivities that are normally part of the EU legal framework (for instance Supplementary Protection Certificates, Pediatric Extensions or Orphan exclusivity). 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-AI Act currently being considered in the EU. If funding** **We may not be able to anticipate how to respond to the these** EMA rapidly evolving frameworks, and we may need to expend resources to adjust our offerings in **certain jurisdictions if the legal frameworks are inconsistent across jurisdictions. Furthermore, because AI technology itself is highly complex** so reduced, it could create delays in the EMA issuing regulatory approvals for our products and **rapidly developing** 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 **not possible to predict all of the legal implications** the withdrawal of the United Kingdom from the EU will have and how such withdrawal will affect us, **operational** and the full extent to which our **or** business could be adversely affected **technological risks that may arise relating to the use of AI.** Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent and other intellectual property protection for our technology, 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~~ **U. S.** 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~~ **U. S.** 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~~ **U. S.** or in other countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable in enforcement and other adversarial proceedings. ~~The Table of Contents~~ **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~~ **U. S.** or in other countries. Our pending **PCT** 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 U. S. may not protect our rights to the same extent as the laws of the United States U. S., and many companies have encountered significant problems in protecting and defending such rights in such jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States U. S. law does. Other parties have developed technologies that may be related or competitive to our own technologies and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own or licensed patent applications or issued patents. Furthermore, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology, 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 U. S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. Patent Table of Contents Patent reform legislation in the United States U. S., including the Leahy- Smith America Invents Act (“the Leahy- Smith Act”), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith Act was signed into law on September 16, 2011 and includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review (“IPR”), and derivation proceedings. After March 15, 2013, under the Leahy- Smith Act, the United States U. S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third -party was the first to invent the claimed invention. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States U. S. and abroad. We are currently and may in the future be subject to third- party pre- issuance submissions of prior art to the USPTO or its equivalents and we or our licensors have in the past, and may in the future, become involved in opposition, derivation, reexamination, IPR 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, on April 23, 2024, a petition for an IPR was filed with three-- the Patent Trial and Appeal Board (“PTAB”) by Encube Ethicals Pvt. Ltd., alleging that certain claims of U. S. Patent No. 11, 590, 088 (the “ ‘088 Patent ”), relating to VTAMA (tapinarof) cream 1 %, are invalid. The ‘088 Patent expires in 2039. The PTAB is not expected to decide whether to institute the IPR until approximately six months from the petition filing date. In February 2023, Sandoz Group AG filed an opposition challenging Dermavant’ s European Patent Number 3297605 which covers topical formulations of tapinarof. The opposition is ongoing and should be decided in the fourth quarter of calendar year 2024. In addition, certain U. S. patents (U. S. Patent Nos. 8, 058, 069, 9, 364, 435 and 9, 404, 127) relating to lipid nanoparticle molar ratios and the aggregation of lipid nanoparticles that Genevant Sciences GmbH, as assignee of Genevant Sciences Ltd. (“Genevant”), exclusively licensed from Arbutus Biopharma Corp. (“Arbutus”) have previously been the subject of IPR inter partes review proceedings brought by Moderna Therapeutics, Inc. (“Moderna”) before the Patent Trial and Appeal Board of the USPTO (“PTAB”), whose decisions were subsequently reviewed by the United States U. S. Court of Appeals for the Federal Circuit (the “Federal Circuit”). The As previously disclosed, the Federal Circuit ultimately (i) affirmed the PTAB’ s decision decisions upholding that upheld all claims of U. S. Patent No. 8, 058, 069; (ii) affirmed the PTAB’ s decision invalidating certain claims under of U. S. Patent No. 9, 364, 435 but dismissed Moderna’ s appeal with respect to those patents claims that the PTAB upheld for lack of standing and (iii) affirmed the PTAB’ s decision invalidating others all claims of U. S. Patent No. 9, 404, 127-. Additionally, one European patent (EU Patent No. EP2279254) relating to lipid nanoparticle molar ratios that Genevant exclusively licensed from Arbutus is the subject of an opposition proceeding brought in 2018 by Merck Sharp & Dohme Corporation and Moderna at the European Patent Office (the “EPO”) Opposition Division. In 2019, the EPO Opposition Division upheld claims as amended by an auxiliary request submitted by the patent owner. Merck and Moderna appealed and, in 2023, the Boards of Appeal of the EPO set aside the EPO Opposition Division decision and remitted the case to the EPO Opposition Division for further prosecution. In March 2024, the EPO Opposition Division issued a preliminary opinion. Oral proceedings are scheduled for June 2024, and the case is pending. Genevant may commence litigation at any time to enforce its patent rights against infringers. The outcome

following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, 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 Table of Contents** 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 U. S.**, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, are limited. Without patent protection 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 U. S.**, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product 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 U. S.** or any other jurisdiction with respect to VTAMA. Instead, we rely on **an-four** issued U. S. **patent-patents** claiming topical formulations of VTAMA, including the **commercial** formulation **which was** studied in Phase 3 trials and approved by the FDA, and **an-two** issued U. S. **patent-patents** 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, **without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees**. We additionally rely on **a-three** drug substance (“DS”) **patent-patents** 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, **without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We also have a patent covering the use of VTAMA to treat psoriasis wherein patients achieve the Phase 3 clinical endpoints. This method of treatment patent is expected to expire in 2040 (including a potential patent term extension for pediatric exclusivity)**. 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 Table of Contents** 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 U. S.** 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 U. S.** and, if available, in other countries where we are prosecuting patents. Depending upon the timing, duration and specifics of FDA marketing approval of product candidates, one or more of our U. S. patents may be eligible for a limited patent term extension (“ PTE ”) under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the **United States U. S.**, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time- period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval for a given product 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 Table of Contents** 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 **IMVT- 1402 or** file or enforce patents relating to these assets in territories other than the **United States U. S.**, Canada, Mexico, the EU, the U. K., Switzerland, the Middle East, North Africa and Latin America, as such rights in other jurisdictions have been retained by HanAll Biopharma Co., Ltd. (“ HanAll ”) or licensed by HanAll to third parties. Additionally, Dermavent 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 U. S.**, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, **IPR 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-Table of ContentsParties** 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-Common Shares-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-U. S.** 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-U. S.** and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U. S. patent applications filed before November 29, 2000 and certain U. S. patent applications filed after that date that will not be filed outside the **United States-U. S.** 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 U. S.** or abroad that we consider relevant may be incorrect and we may incorrectly conclude that a third- party patent is invalid or unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our 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 Table of Contents Competitors** may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time- consuming, even if ultimately successful. For example, in February 2022, Roivant’ s subsidiary, Genevant Sciences GmbH (“ Genevant GmbH ”), and Arbutus filed a lawsuit in the U. S. District Court for the District of Delaware against Moderna and an affiliate seeking damages for infringement of U. S. Patent Nos. 8, 058, 069, 8, 492, 359, 8, 822, 668, 9, 364, 435, 9, 504, 651, and 11, 141, 378 in the manufacture and sale of MRNA- 1273, Moderna’ s vaccine for COVID- 19 (the “ Moderna Action ”). In November 2022, the District Court denied Moderna’ s partial motion to dismiss pursuant to 28 U. S. C. § 1498 (a) (“ § 1498 ”). In March 2023, following the submission of a Statement of Interest in the case by the **United States U. S.** Government, the court reaffirmed its prior decision and again ruled that the complaint should not be partially dismissed on the basis of § 1498. **In March On February 8, 2022-2024**, **Acutas Therapeutics Inc. filed a lawsuit in the United States District Court court for held a Claim Construction hearing on disputed terms within the claims Southern District of New York against the asserted patents. On April 3, 2024, the court provided its Claim Construction ruling, in which it construed the disputed claim terms and agreed with Genevant GmbH and Arbutus’ position on most of seeking a declaratory judgment that U. S. Patent Nos. 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 disputed claim terms. Fact discovery is ongoing and next steps include expert reports and depositions. A trial date has been set for sale April 21, 2025 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 ”). Genevant GmbH and Arbutus have moved to dismiss the Acuitas Action and that motion is pending before the District Court.** On April 4, 2023, Genevant GmbH and Arbutus filed a lawsuit in the U. S. District Court for the District of New Jersey against Pfizer and BioNTech seeking damages for infringement of U. S. Patent Nos. 9, 504, 651, 8, 492, 359, 11, 141, 378, 11, 298, 320 and 11, 318, 098 in the manufacture and sale of COMIRNATY (the “ Pfizer Action ”). **On July 10, 2023, Genevant GmbH and Arbutus expect a response from Pfizer and BioNTech later this calendar year filed an answer. The Pfizer Action is ongoing and a date for a claim construction hearing has not been set.** 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 **Acutas Pfizer** Action, will ultimately be resolved successfully. Further, even if we prevail against an infringer in U. S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and / or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly in a manner insufficient to achieve our business objectives, or could put our patent applications at risk of not issuing. The initiation of a claim against a third -party may also cause the third- party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the **United States U. S.**, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or lack of written description or non- statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, **IPR** inter partes review, or post- grant review, or oppositions or similar proceedings outside the **United States U. S.**, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against claims 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 U. S.** Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in

connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ~~Common~~ **common Shares** ~~shares~~. ~~We~~ **Table of Contents** ~~We~~ may not have sufficient financial or other resources to adequately conduct the Moderna Action, the ~~Acuitas~~ **Pfizer** Action or any other such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Because of the expense and uncertainty of litigation, we may conclude that even if a third ~~party~~ is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. Because many of the patents we own or have licensed are owned or licensed by our subsidiaries, and in certain cases by subsidiaries that are not or will not be directly commercializing products, we may not be in a position to obtain a permanent injunction against a third ~~party~~ that is found to infringe our patents. Many patents that we own or have licensed are assigned to or licensed by our direct or indirect subsidiaries. For example, any patents that Immunovant has licensed are assigned to its wholly-owned subsidiary Immunovant Sciences GmbH 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~~ **U. S.** or other jurisdictions when the patent is assigned to a subsidiary, which is not the entity that is or would be commercializing a potentially competitive product or service. In such a circumstance, such third-party may be able to compete with us or our subsidiaries, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Changes in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our 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~~ **U. S.** or USPTO rules and regulations could increase the uncertainties and costs. The ~~United States~~ **U. S.** has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. For example, **in June 2022**, the Biden administration has indicated its support for a proposal at the World Trade Organization **members agreed** to waive **certain** patent rights with respect to COVID-19 vaccines. Any waiver of our patent or other intellectual property protection by the U. S. and other foreign governments, including with respect to Genevant's licensed lipid nanoparticle ("LNP") delivery technology as used in connection with messenger RNA vaccine delivery, could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Depending on actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by ~~United States~~ **U. S.** and non-U. S. legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. ~~In~~ **Table of Contents** ~~In~~ addition, the ~~United States~~ **U. S.** federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." For example, the research resulting in certain of our acquired or in-licensed patent rights and technology for certain 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~~ **U. S.** We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh- Dole Act at all times or be able to rectify any lapse in compliance with these requirements. Any exercise by the government of any of the foregoing rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. The validity, scope and enforceability of any patents listed in the Orange Book that cover our 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 Table of Contents** 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~~ **U. S.** can be less extensive than those in the ~~United States~~ **U. S.** The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws of the ~~United States~~ **U. S.** Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the ~~United States~~ **U. S.**, or from selling or importing product candidates made using our inventions in and into the ~~United States~~ **U. S.** 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~~ **U. S.** 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 Table of Contents** 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~~ **U. S.** are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors and other third parties may discover our trade secrets, including our proprietary software, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's or other third-party's discovery of our trade secrets, including our proprietary software, would impair our competitive position and have an adverse impact on our business. We cannot guarantee that we have entered into non-disclosure, confidentiality agreements, material transfer agreements or consulting agreements with each party that may have or have had access to our trade secrets or proprietary software, technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and proprietary software, and we may not be able to obtain adequate remedies for such breaches. Monitoring

unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States U. S. are less willing or unwilling to protect trade secrets. If any of our trade secrets, including our proprietary software, were to be lawfully obtained or independently developed by a competitor or other third- party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, including our proprietary software, were to be disclosed to or independently developed by a competitor or other third- party, our competitive position would be harmed. Certain software utilized in our computational drug discovery efforts may include third- party open source software. Any failure to comply with the terms of one or more open source software licenses could adversely affect our business, subject us to litigation, or create potential liability. Certain software utilized in our computational drug discovery efforts may include third- party open source software and we expect to continue to incorporate open source software in the future. The use of open source software involves a number of risks, many of which cannot be eliminated and could negatively affect our business. For example, we cannot ensure that we have effectively monitored our use of open source software or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming infringement on such third parties' intellectual property rights. Litigation could be costly for us to defend, have a negative effect on our business, financial condition and results of operations, or require us to devote additional research and development resources to modify our computational drug discovery platform. Use Table of ContentsUse 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. **Table of Intellectual ContentsIntellectual** property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities, and have a harmful effect on the success of our business. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, including the Moderna Action, **and** the Pfizer Action 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 common Shares 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 U. S.** and in other jurisdictions may not be allowed or may subsequently be opposed, challenged, infringed, circumvented, declared generic or determined to be infringing other marks. Additionally, once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties have in the past opposed, are currently opposing and may in the future oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand 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 Table of ContentsWe** may not be able to protect our rights to these

trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, **IPR** ~~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 U. S.** and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable; • third parties performing manufacturing or testing for us using our products, product candidates or technologies could use the intellectual property of others without obtaining a proper license; **Table of Contents** • 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 common Shares shares** may decline. In addition, the trading price of our **Common common Shares shares** could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on the price of our **Common common Shares shares**. Factors affecting the trading price of our **Common common Shares 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 common Shares 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 common Shares shares** available for public sale and the relatively limited free float of our **Common common Shares shares**; • any significant change in our board of directors or management; • sales of substantial amounts of our **Common common Shares shares** by directors, executive officers or significant shareholders or the perception that such sales could occur; **and and Table of Contents** • 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 common Shares 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 common Shares 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 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 the holder's approval. Our Warrants were initially issued by Montes Archimedes Acquisition Corp. ("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 be expected to increase even more from March 31, 2024, after which date we are were** no longer an emerging growth company, as defined in Section 2 (a) of the Securities Act. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the Dodd- Frank Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq. **We also expect that compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and increased disclosure requirements will substantially increase our legal and financial compliance costs.** Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time- consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain blended director and officer liability insurance and forced us to forego securities and corporate protection coverage. We cannot predict or estimate the amount or timing of additional costs we have incurred and will continue to incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract~~



and retain qualified persons to serve on our board of directors, our board committees or as executive officers. 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 **fail** 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 **maintain proper and** 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, **our** provides reasonable assurance regarding the reliability **ability of to produce accurate and timely financial statements could be impaired, investors may lose confidence in our** financial reporting and the preparation **trading price of our common shares may decline** financial statements for external purposes in accordance with U.S. **Pursuant to Section 404 S-** GAAP, because of **the Sarbanes-Oxley Act, our management** its **is** inherent limitations, **required to report upon the effectiveness of our** internal control over financial reporting, **and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting.** The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and costly. **If we or our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common shares may decline.** Although we have **determined that our internal control over financial reporting was effective as of March 31, 2024, we cannot assure you that there will** not prevent **be material weaknesses or significant deficiencies in or our internal** detect fraud or misstatements. Failure to implement required new or improved controls **control over financial reporting**, or difficulties encountered in their **the** implementation, **future. Any failure to maintain internal control over financial reporting could harm adversely impact** our ability to accurately and timely report our financial condition, results of operations or **cash flows** cause us to fail to meet our future reporting obligations. We may redeem unexpired Warrants prior to their exercise at a time that is disadvantageous to holders, thereby making the 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 we 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 **conclude that** effect such registration or **our** qualification. We will use **internal control over financial reporting is effective, our** or best efforts to **if our independent** register **registered public accounting firm determines we have a material weakness or significant deficiency in or our internal control over financial reporting,** 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 **investors** to (i) to exercise their Warrants and pay the exercise price therefor at a time when it may **lose confidence in** be disadvantageous for an investor to do so, (ii) for an investor to sell their Warrants at the then **the** current **accuracy and completeness of our financial reports, the** market price **of** when they might otherwise wish to hold their Warrants or **our common shares could decline and we could** (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 **subject to sanctions or investigations by Nasdaq, the SEC or the other regulatory authorities** market value of an investors Warrants. **Failure to remedy** In addition, we may redeem an investor's Warrants at any **material weakness in** 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, provided that the last reported sales price of our Common Shares is equal to or **our internal control over financial reporting,** exceeds \$ 10. 00 per share (as adjusted for **or to implement** share sub divisions, share capitalizations, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for **or maintain** any 20 trading days within a 30 trading day period ending on the third trading day prior to the date we send the notice of redemption to the warrant holders. 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 Patient Square or its permitted transferees. Our management has 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 Patient Square, MAAC's former officers or directors, other **effective control systems** purchasers of MAAC's founders' units, or their permitted transferees) to do so on a "cashless basis." If our management chooses to require **required** holders to exercise their Warrants on a cashless basis, the number of **public companies**, Common Shares received by a holder upon exercise will be fewer than it would **could also restrict** 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 **future access to the capital markets**. Changes in laws or regulations, or a failure to comply with any laws and regulations, may adversely affect our business, investments and results of operations. We are subject to laws and regulations enacted by national, regional and local governments. In particular, we will be required to comply with certain SEC and other legal requirements. Compliance with, and monitoring of, applicable laws and regulations may be difficult, time consuming and costly. Those laws and regulations and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with applicable laws or regulations, as interpreted and applied, could have a material adverse effect on our business and results of operations. **Anti-Table of ContentsAnti**-takeover provisions in our memorandum of association and bye-laws, as well as provisions of Bermuda law could delay or prevent a change in control, limit the price investors may be willing to pay in the future for our **Common-common Shares-shares** and could entrench management. Our memorandum of association and bye-laws contain provisions that could make it more difficult for a third-party to acquire us without the consent of our board of directors. These provisions provide for: • a classified board of directors with staggered three-year terms; • the ability of our board of directors to determine the powers, preferences and rights of preference shares and to cause us to issue the preference shares without shareholder approval; and • requiring advance notice for shareholder proposals and nominations and placing limitations on convening shareholder meetings. These provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors of your choosing and cause us to take corporate actions other than those you desire, any of which could harm our share price. Our largest shareholders own a significant percentage of our **Common-common Shares-shares** and are able to exert significant control over matters subject to shareholder approval. Our largest shareholders continue to hold a significant percentage of our **Common-common Shares-shares**. As a result, these holders have the ability to substantially influence us and exert significant control through this ownership position and, in the case of certain holders, service on our board of directors. For example, these holders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. These holders' interests may not always coincide with our corporate interests or the interests of other shareholders, and they may exercise their voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Furthermore, our largest shareholders may from time to time have interests that differ from ours or from one another, and from time to time there may be disputes with or between such shareholders, which could be costly, time-consuming and divert management resources. So long as these holders continue to own a significant amount of our equity, they will continue to be able to strongly influence our decisions. Future sales and issuances of our or the Vants' equity securities or rights to purchase equity securities, including pursuant to our or the Vants' equity incentive and other compensatory plans, will result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall. We and the Vants **will-may** 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-common Shares-shares**, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. In addition, new investors could gain rights superior to our existing shareholders. Pursuant to our 2021 Equity Incentive Plan (the "2021 EIP"), we are authorized to grant options, restricted stock units and other share-based awards to our employees, directors and consultants. The aggregate number of shares initially reserved for issuance under the 2021 EIP increases annually on the first day of each fiscal year during the term of the plan in an amount equal to the lesser of (i) 5% of the number of our **Common-common Shares-shares** outstanding as of the day of the immediately preceding fiscal year and (ii) such number of our **Common-common Shares-shares** as determined by our board of directors in its discretion. As a result of this annual increase, or if our board of directors elects in the future to make any additional increase in the number of shares available for future grant under the 2021 EIP, and if our shareholders approve of any such additional increase, our shareholders may experience additional dilution, and our share price may fall. Issuance of options, restricted stock units and other share-based awards pursuant to equity incentive plans at the Vants may indirectly have a similar effect of diluting your ownership in us since a portion of the value of our **Common-common Shares-shares** is tied to the value of the Vants, which would be diluted in the event of a grant of options or other similar equity grants to the employees of the Vants. **Future-Table of ContentsFuture** sales, or the perception of future sales, of our **Common-common Shares-shares** by us or our existing shareholders **in the public market** could cause the market price for our **Common-common Shares-shares** to decline and impact our ability to raise capital in the future. Sales of a substantial number of our **Common-common Shares-shares** **in the public market** by us or certain of our existing large shareholders, or the perception that these sales could occur, could substantially decrease the market price of our **Common-common shares**. **As held by certain** of our **March 31, 2023**, these large shareholders held approximately 70.7% of our issued and outstanding Common Shares. These shares have been registered for re-sale pursuant to a registration statement on Form S-3 and may also be sold pursuant to Rule 144 under the Securities Act, subject to certain restrictions (including restrictions applicable to affiliates in the case of shares held by persons deemed to be our affiliates). **While certain of our significant shareholders are subject to contractual lock-up agreements as described under the heading "Lock-Up Agreements"**

in the description of our share capital attached as exhibit 4.5 to this annual report on Form 10-K, these lock-up agreements are subject to significant limitations and expire by their terms on February 29, 2024. The market price of our Common common Shares shares could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. This, in turn, could also make it more difficult for us to raise additional funds through future offerings of our Common common Shares shares or other securities at prices that are attractive to us, or at all. If securities analysts publish negative evaluations of our shares, the price of our Common common Shares 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 common Shares shares adversely, or provide more favorable relative recommendations about its competitors, the price of our Common common Shares shares would likely decline. If any analyst who may cover us were to cease coverage or fail to regularly publish reports, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Because there are no current plans to pay cash dividends on our Common common Shares shares for the foreseeable future, you may not receive any return on investment unless you sell our Common common Shares shares for a price greater than that which you paid for it. We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions, applicable law and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our Common common Shares 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 Table of Contents 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 common Shares 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 common Shares 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 common Shares 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 Table of Contents** judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws (including tax treaties), regulations, principles, and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. We continue to assess the impact of such changes in tax laws and interpretations on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows. Changes in our effective tax rate may reduce our net income in future periods. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U. K. and Switzerland), the U. S., Bermuda and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co- operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition. Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock- based compensation; (6) changes in tax laws (including tax treaties) or the interpretation of such tax laws (including tax treaties) and changes in U. S. generally accepted accounting principles; (7) challenges to the transfer pricing policies related to our structure; (8) potential taxation under the OECD BEPS 2. 0; and (9) potential limitation on tax attributes due to ownership changes (i. e. Internal Revenue Code 382 and 383) or expiration. U. S. holders that own 10 % or more of the combined voting power or value of our **Common common Shares 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 were~~ not be classified as a CFC for the taxable year ended March 31, 2023-2024. However, our non-U. S. subsidiaries will be classified as CFCs for the taxable year ended March 31, 2023-2024. For U. S. holders who hold 10 % or more of the combined voting power or value of our ~~Common common Shares 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 common Shares shares~~, you should consult your own tax advisors regarding the U. S. tax consequences of acquiring, owning, or disposing of our ~~Common common Shares shares~~. [U Table of Contents](#) U. S. holders of our ~~Common common Shares shares~~ may suffer adverse tax consequences if we are characterized as a passive foreign investment company. Generally, if, for any taxable year, at least 75 % of our gross income is passive income, or at least 50 % of the average quarterly value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company (a " PFIC ") for U. S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, if we own (directly or indirectly) at least 25 % (by value) of the stock of another corporation, for purposes of determining whether we are a PFIC, generally we would be treated as if we held our proportionate share of the assets of such other corporation and received directly our proportionate share of the income of such other corporation and generally we would retain the character of such assets and income as if they were held directly by us rather than by such other corporation. If we are characterized as a PFIC, U. S. holders of our ~~Common common Shares shares~~ may suffer adverse tax consequences, including having gains realized on the sale of our ~~Common common Shares shares~~ treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our ~~Common common Shares 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 common Shares 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 common Shares shares~~ should be considered to be " publicly traded " for the taxable years ending on March 31, 2022 and March 31, 2023, we would apply the 50 % passive asset test using the fair market value of our assets. In addition, our status may also depend, in part, on how quickly we utilize our cash on- hand and cash from future financings in our business. Treasury regulations adopted in 2021 (the " 2021 Regulations ") modify certain of the rules described above. The 2021 Regulations generally apply to taxable years of shareholders beginning on or after January 14, 2021. A shareholder, however, may choose to apply such rules for any open taxable year beginning before January 14, 2021, provided that, with respect to a non- U. S. corporation being tested for PFIC status, the shareholder consistently applies certain of the provisions of the 2021 Regulations and certain other Treasury regulations for such year and all subsequent years. Investors who are U. S. holders should consult their own tax advisors regarding the impact and applicability of the 2021 Regulations. Based on the foregoing, with respect to the taxable year that ended on March 31, 2023-2024, we believe that ~~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 were not a PFIC based in part on - hand and cash from future financings our belief that we were not classified as a CFC in our business. Based on the foregoing, with respect to~~ the taxable year that ended on March 31, 2023-2024 and, we believe that we were not a PFIC based ~~in part~~ upon the fair market value of our assets, including any goodwill and intangible property, and the nature and composition of our income and assets. Our status as a PFIC is a fact- intensive determination made on an annual basis, which is subject to uncertainties, including but not limited to the fact that the value of our assets for purposes of the PFIC determination may be affected by the trading value of our ~~Common common Shares shares~~, which could fluctuate significantly. The total value of our assets for purposes of the PFIC asset test frequently (though not invariably) may be inferred using the market price of our ordinary shares, which may fluctuate considerably and thereby affect the determination of our PFIC status for future taxable years. Our U. S. counsel expresses no opinion with respect to our PFIC status for the current or future taxable years. We will endeavor to determine our PFIC status for each taxable year and make such determination available to U. S. holders. [ITEM Table of Contents](#) [ITEM](#) 1.B. UNRESOLVED STAFF COMMENTS None. [ITEM 2. PROPERTIES](#) Our principal executive offices are located at 7th Floor, 50 Broadway, London SW1H 0DB, United Kingdom. Our registered office is located at

Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. 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 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. As of June 26, 2023, there were 100 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** None.

**Issuer Repurchases of Equity Securities** None.

**ITEM 6. [RESERVED]**

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS** The following discussion and analysis of Roivant's financial condition and results of operations should be read in conjunction with Roivant's consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Roivant's actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. Please see "Forward-Looking Statements" and "Risk Factors" in this Annual Report on Form 10-K. Our fiscal year ends on March 31 and our fiscal quarters end on June 30, September 30 and December 31.

**Overview** Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant's pipeline is concentrated in inflammation and immunology and includes VTAMA, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batochimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fe receptor ("FeRn") in development across several IgG-mediated autoimmune indications; and RVT-3101, an anti-TL1A antibody in development for ulcerative colitis and Crohn's disease, in addition to several other therapies in various stages of clinical development. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business.

**Components of Results of Operations**

**Product revenue, net** With the FDA approval of VTAMA for the treatment of plaque psoriasis in adult patients and our initial product launch in May 2022, we began to recognize product revenues. We record product revenue net of estimated chargebacks, discounts, rebates, returns, and other allowances associated with the respective sales. License, milestone and other revenue License, milestone and other revenue includes the recognition of upfront payments received in connection with license agreements as well as revenue generated by subscription and service-based fees.

**Cost of revenues** We began to recognize cost of product revenues after the initial product launch of VTAMA in May 2022. Cost of product revenues includes the cost of producing and distributing inventories related to product revenue during the respective period, including manufacturing, freight, and indirect overhead costs. Additionally, milestone payments made in connection with regulatory approvals and sales-based milestones are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Our cost of revenues also relates to subscription and service-based revenue recognized for the use of technology developed and consists primarily of employee, hosting, and third-party data costs.

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

- Program-specific costs, including direct third-party costs, which include expenses incurred under agreements with contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of our product candidates.
- Unallocated internal costs, including: ◦ employee-related expenses, such as salaries, share-based compensation, and benefits, for research and development personnel; and ◦ other expenses that are not allocated to a specific

program. Research and development activities will continue to be central to our business model. We anticipate that our research and development expenses will increase for the foreseeable future as we advance our product candidates and our recently in-licensed assets through preclinical studies and clinical trials, as well as acquire or discover new product candidates. We expect higher employee-related expenses, including share-based compensation expenses, as well as higher consulting costs as we hire additional resources to support increasing development activity. The duration, costs and timing of preclinical studies and clinical trials of our product candidates will depend on a variety of factors that include, but are not limited to, the following: • the scope, rate of progress, expense and results of our preclinical development activities, any future clinical trials of our product candidates, and other research and development activities that we may conduct; • the number and scope of preclinical and clinical programs we decide to pursue; • the uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates; • the number of doses that patients receive; • the countries in which the trials are conducted; • our ability to secure and leverage adequate CRO support for the conduct of clinical trials; • our ability to establish an appropriate safety and efficacy profile for our product candidates; • the timing, receipt and terms of any approvals from applicable regulatory authorities; • the potential additional safety monitoring or other studies requested by regulatory agencies; • the significant and changing government regulation and regulatory guidance; • our ability to establish clinical and commercial manufacturing capabilities, or make arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully; • the impact of any business interruptions to our operations due to the COVID-19 pandemic or other epidemics; and • our ability to maintain a continued acceptable safety profile of our product candidates following approval of our product candidates. The successful development of our product candidates is highly uncertain, and we cannot reasonably estimate the costs that will be necessary to complete the remainder of the development of our product candidates. In addition, the probability of success for our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. Acquired-in-process research and development expenses Acquired-in-process research and development (“IPR & D”) expenses include consideration for the purchase of IPR & D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones. Consideration for the purchase of IPR & D through asset acquisitions and license agreements includes cash upfront payments, shares and other liability instruments issued, and fair value of future contingent consideration payments. Selling, general and administrative expenses Selling, general and administrative (“SG & A”) expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, sales incentive compensation, and benefits, for employees engaged in SG & A activities. SG & A employees include those responsible for the identification and acquisition or in-license of new drug candidates as well as for managing Vant operations and facilitating the use of our platform and technologies at the Vants. SG & A expenses also consist of marketing programs, advertising, legal and accounting fees, consulting services, and other operating costs relating to corporate matters and daily operations. Additionally, SG & A expenses include costs incurred relating to the identification, acquisition or in-license and technology transfer of promising drug candidates along with costs incurred relating to the integration of new technologies. We expect SG & A expenses to increase in future periods as we continue to expand our sales and marketing infrastructure and general administrative functions. These increases will likely include salaries, sales incentive compensation, share-based compensation and travel expenses associated with our sales force, which began promoting VTAMA in the United States following approval by the FDA in May 2022, as well as expected costs associated with the further build out of our commercial operations functions. We anticipate these expenses to further increase if any of our other current or future product candidates receives regulatory approval in the United States or another jurisdiction. Change in fair value of investments Change in fair value of investments primarily includes the unrealized loss on equity investments in publicly-traded companies, including Arbutus Biopharma Corporation (“Arbutus”), as well as our equity investment in Heraclis Parent, L. L. C., the parent entity of the Datavant business (“Datavant”). We have elected the fair value option to account for these investments. Change in fair value of debt and liability instruments Change in fair value of debt and liability instruments primarily includes the unrealized loss (gain) relating to the measurement and recognition of fair value on a recurring basis of certain liabilities, including debt issued by a wholly-owned subsidiary of Dermavant Sciences Ltd. to NovaQuest Co-Investment Fund VIII, L. P. (the “NovaQuest Facility”), and other liability instruments, including warrant and earn-out share liabilities issued in connection with our business combination (the “Business Combination”) with Montes Archimedes Acquisition Corp. (“MAAC”), a special purpose acquisition company. Gain on deconsolidation of subsidiaries Gain on deconsolidation of subsidiaries resulted from the determination that we no longer had a controlling financial interest in certain subsidiaries. Interest income Interest income consists of interest earned on our cash equivalents. Interest expense Interest expense results from interest accrued on long-term debt and the amortization of debt discount and issuance costs. Income tax expense Income tax expense is recorded for the jurisdictions in which we do business. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that our deferred tax assets will be realizable. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. Income from discontinued operations, net of tax Income from discontinued operations, net of tax represents the gain on sale of common shares of Myovant Sciences Ltd. (“Myovant”) as a result of Sumitovant Biopharma Ltd.’s (“Sumitovant”) acquisition of Myovant in March 2023. We were entitled to these shares of Myovant pursuant to the December 2019 transaction with Sumitomo Pharma Co., Ltd. (the “Sumitomo Transaction”) that included, among other things,

the transfer of our ownership interest in five Vants to Sumitovant. The Sumitomo Transaction was presented as discontinued operations during the year ending March 31, 2020, and the right to receive certain common shares of Myovant was treated as a contingent consideration upon a sale of the business and accounted for as a gain contingency. 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, 2023 and 2022 The following table sets forth our results of operations for the years ended March 31, 2023 and 2022: Years Ended March 31, 2023 Change (in thousands) Revenues: Product revenue, net \$ 28, 011 \$ — \$ 28, 011 License, milestone and other revenue 33, 269 55, 286 (22, 017) Revenue, net 61, 280 55, 286 \$ 5, 994 Operating expenses: Cost of revenues 13, 128 8, 966 4, 162 Research and development 525, 215 483, 035 42, 180 Acquired in-process research and development 97, 749 139, 894 (42, 145) Selling, general and administrative 600, 506 775, 033 (174, 527) Total operating expenses 1, 236, 598 1, 406, 928 (170, 330) Loss from operations (1, 175, 318) (1, 351, 642) 176, 324 Change in fair value of investments 20, 815 87, 291 (66, 476) Gain on sale of investment — (443, 754) 443, 754 Change in fair value of debt and liability instruments 78, 001 (3, 354) 81, 355 Gain on termination of Sumitomo Options — (66, 472) 66, 472 Gain on deconsolidation of subsidiaries (29, 276) (5, 041) (24, 235) Interest income (32, 184) (369) (31, 815) Interest expense 27, 968 7, 041 20, 927 Other income, net (15, 808) (3, 237) (12, 571) Loss from continuing operations before income taxes (1, 224, 834) (923, 747) (301, 087) Income tax expense 5, 190 4, 821 Loss from continuing operations, net of tax (1, 230, 024) (924, 116) (305, 908) Income from discontinued operations, net of tax 114, 561 — 114, 561 Net loss (1, 115, 463) (924, 116) (191, 347) Net loss attributable to noncontrolling interests (106, 433) (78, 854) (27, 579) Net loss attributable to Roivant Sciences Ltd. \$ (1, 009, 030) \$ (845, 262) \$ (163, 768) Variance analysis for years ended March 31, 2023 and 2022 Product revenue, net Years Ended March 31, 2023 Change (in thousands) Product revenue, net \$ 28, 011 \$ — \$ 28, 011 Product revenue, net was \$ 28. 0 million for the year ended March 31, 2023, consisting of net product revenues from the sale of VTAMA, following the approval of VTAMA for the treatment of plaque psoriasis in adult patients by the FDA in May 2022. We did not generate any product revenues, net for the year ended March 31, 2022. License, milestone and other revenue Years Ended March 31, 2023 Change (in thousands) License, milestone and other revenue \$ 33, 269 \$ 55, 286 \$ (22, 017) License, milestone and other revenue decreased by \$ 22. 0 million to \$ 33. 3 million for the year ended March 31, 2023, compared to \$ 55. 3 million for the year ended March 31, 2022. During the year ended March 31, 2023, license, milestone and other revenue primarily related to payments received in connection with licensing arrangements, including the collaboration and license agreement entered between Covant Therapeutics Operating, Inc. and Boehringer Ingelheim International, GmbH in March 2023. During the year ended March 31, 2022, license, milestone and other revenue primarily related to payments received in connection with license agreements and the licensing of technology as well as revenue relating to the sales of clinical product and milestone income at Dermavant pursuant to a collaboration and license agreement with Japan Tobacco Inc. Cost of revenues For the years ended March 31, 2023 and 2022, our cost of revenues consisted of the following: Years Ended March 31, 2023 Change (in thousands) Cost of product and other revenues \$ 5, 660 \$ 8, 966 \$ (3, 306) Amortization of intangible assets 7, 468 — 7, 468 Cost of revenues \$ 13, 128 \$ 8, 966 \$ 4, 162 Cost of revenues increased by \$ 4. 2 million to \$ 13. 1 million for the year ended March 31, 2023, compared to \$ 9. 0 million for the year ended March 31, 2022. During the year ended March 31, 2023, cost of revenues included \$ 1. 8 million of costs relating to the sale of VTAMA as well as \$ 7. 5 million of amortization expense recognized in connection with milestones capitalized following the FDA approval of VTAMA in May 2022. During the year ended March 31, 2022, cost of revenues was primarily related to cost associated with the sales of clinical product of tapinarof by Dermavant to Japan Tobacco Inc. Research and development expenses For the years ended March 31, 2023 and 2022, our research and development expenses consisted of the following: Years Ended March 31, 2023 2022 (1) Change (in thousands) Program-specific costs: Anti-FeRn franchise (2) \$ 88, 747 \$ 52, 009 \$ 36, 738 Tapinarof 45, 201 64, 496 (19, 295) Brepocitinib 38, 627 24, 890 13, 737 RVT-2001 16, 075 1, 132 14, 943 AFVT-2101 15, 628 12, 657 2, 971 ARU-1801 12, 940 23, 312 (10, 372) Namilumab 11, 757 8, 745 3, 012 RVT-3101 7, 559 — 7, 559 LSVT-1701 7, 173 11, 067 (3, 894) ARU-2801 3, 456 12, 031 (8, 575) Other development and discovery programs 83, 680 74, 700 8, 980 Total program-specific costs 330, 843 285, 039 45, 804 — Unallocated internal costs: Share-based compensation 30, 914 63, 735 (32, 821) Personnel-related expenses 131, 908 103, 827 28, 081 Other expenses 31, 550 30, 434 1, 116 Total research and development expenses \$ 525, 215 \$ 483, 035 \$ 42, 180 (1) Certain prior year amounts have been reclassified to conform to current year presentation. (2) Reflects program-specific costs relating to Immunovant's batoelimab program for the treatment of neurology, endocrine, and hematology diseases and Immunovant's IMVT-1402 program. Research and development expenses increased by \$ 42. 2 million to \$ 525. 2 million for the year ended March 31, 2023, compared to \$ 483. 0 million for the year ended March 31, 2022, primarily due to increases in program-specific costs of \$ 45. 8 million and personnel-related expenses of \$ 28. 1 million, partially offset by a decrease in share-based compensation of \$ 32. 8 million. The increase of \$ 45. 8 million in program-specific costs largely reflects the progression of our programs and drug discovery, including the anti-FeRn franchise, RVT-2001, brepocitinib, and RVT-3101. The asset acquisitions of brepocitinib, RVT-2001, and RVT-3101 were completed in September 2021, November 2021, and November 2022, respectively. Increases in program-specific costs were partially offset by certain decreases, including \$ 19. 3 million for tapinarof, which was primarily due to the completion of ADORING 1 and ADORING 2 phase 3 atopic dermatitis clinical trials during the year ended March 31, 2023. The increase of \$ 28. 1 million in personnel-related expenses largely reflects the progression of our programs, particularly the anti-FeRn franchise. Personnel-related expenses increased at Immunovant primarily as a result of higher headcount and enhancement of capabilities to support Immunovant's strategic objectives as clinical activities were resumed and potential new indications were evaluated. The decrease of \$ 32. 8 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. Acquired in-process research and development expenses Years Ended March 31, 2023 Change (in thousands) Consideration for the purchase of IPR & D \$ 87,749 \$ 97,412 \$ (9,663) Development milestone payments 10,000 42,482 (32,482) Total acquired in-process research and development expenses \$ 97,749 \$ 139,894 \$ (42,145) Acquired in-process research and development expenses decreased by \$ 42.1 million to \$ 97.7 million for the year ended March 31, 2023, compared to \$ 139.9 million for the year ended March 31, 2022. The decrease was primarily due to higher consideration for the purchase of IPR & D during the year ended March 31, 2022 as a result of consideration for the purchase of IPR & D of \$ 82.1 million relating to the acquisition of brepocitinib, a one-time milestone expense of approximately \$ 39 million due to the achievement of a development milestone related to tapinarof, and consideration for the purchase of IPR & D of \$ 14.1 million relating to the acquisition of RVT-2001. Acquired in-process research and development expenses for the year ended March 31, 2023 was driven by consideration for the purchase of IPR & D of \$ 87.7 million relating to the acquisition of RVT-3101 and the achievement of a development milestone relating to batoelimab, which resulted in a one-time milestone expense of \$ 10.0 million. Selling, general and administrative expenses Years Ended March 31, 2023 Change (in thousands) Selling, general and administrative \$ 600,506 \$ 775,033 \$ (174,527) Selling, general and administrative expenses decreased by \$ 174.5 million to \$ 600.5 million for the year ended March 31, 2023, compared to \$ 775.0 million for the year ended March 31, 2022. The decrease was primarily due to a decrease in share-based compensation expense of \$ 314.6 million, partially offset by higher selling, general and administrative expenses at Dermavant as a result of the commercial launch of VTAMA. The decrease in share-based compensation resulted from 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 for the year ended March 31, 2022 for cumulative service rendered between the grant date of the respective awards and completion of the Business Combination. Change in fair value of investments Years Ended March 31, 2023 Change (in thousands) Change in fair value of investments \$ 20,815 \$ 87,291 \$ (66,476) Change in fair value of investments was an unrealized loss of \$ 20.8 million and unrealized loss of \$ 87.3 million for the years ended March 31, 2023 and 2022, respectively. The change of \$ 66.5 million was primarily driven by changes in the public share prices of our equity investments, including Arbutus, as well as the change in fair value of our investment in Datavant following the completion of the Datavant Merger (as defined below) in July 2021. Gain on sale of investment Years Ended March 31, 2023 Change (in thousands) Gain on sale of investment \$ — \$ (443,754) \$ 443,754 Gain on sale of investment was \$ 443.8 million for the year ended March 31, 2022 and resulted from Datavant's merger with a wholly-owned subsidiary of Heraeas Parent, L.L.C., the parent company of CIOX Health, (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. Change in fair value of debt and liability instruments Years Ended March 31, 2023 Change (in thousands) Change in fair value of debt and liability instruments \$ 78,001 \$ (3,354) \$ 81,355 Change in fair value of debt and liability instruments was an unrealized loss of \$ 78.0 million and unrealized gain of \$ 3.4 million for the years ended March 31, 2023 and 2022, respectively. Change in fair value of debt and liability instruments for the year ended March 31, 2023 primarily consisted of an unrealized loss of \$ 59.6 million relating to the NovaQuest facility, which was primarily due to the impact of VTAMA approval in psoriasis, and an unrealized loss of \$ 24.1 million relating to the warrant and earn-out share liabilities issued as part of the Business Combination. Change in fair value of debt and liability instruments 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. Gain on termination of Sumitomo Options Years Ended March 31, 2023 Change (in thousands) 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 an Asset Purchase Agreement entered into with Sumitomo Pharma Co., Ltd. and its subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. Gain on deconsolidation of subsidiaries Years Ended March 31, 2023 Change (in thousands) Gain on deconsolidation of subsidiaries \$ (29,276) \$ (5,041) \$ (24,235) Gain on deconsolidation of subsidiaries was \$ 29.3 million for the year ended March 31, 2023 and resulted from the deconsolidation of certain subsidiaries in November 2022 and July 2022. Gain on deconsolidation of subsidiaries was \$ 5.0 million for the year ended March 31, 2022 and resulted from the deconsolidation of a subsidiary in January 2022. Interest income Years Ended March 31, 2023 Change (in thousands) Interest income \$ (32,184) \$ (369) \$ (31,815) Interest income increased by \$ 31.8 million to \$ 32.2 million for the year ended March 31, 2023, compared to \$ 0.4 million for the year ended March 31, 2022. The increase is primarily the result of higher interest rates on our invested cash. Interest expense Years Ended March 31, 2023 Change (in thousands) Interest expense \$ 27,968 \$ 7,041 \$ 20,927 Interest expense increased by \$ 20.9 million to \$ 28.0 million for the year ended March 31, 2023, compared to \$ 7.0 million for the year ended March 31, 2022. The increase primarily resulted from Dermavant's revenue interest purchase and sale agreement (the "RIPSA"), pursuant to which funding of \$ 160.0 million was received in June 2022 following the approval of VTAMA by the FDA in May 2022. Income from discontinued operations, net of tax Years Ended March 31, 2023 Change (in thousands) Income from discontinued operations, net of tax \$ 114,561 \$ — \$ 114,561 Income from discontinued operations, net of tax was \$ 114.6 million for the year ended March 31, 2023 and resulted from the gain on sale of common shares of Myovant (the "Myovant Top-Up Shares") after Sumitovant's acquisition of Myovant in March 2023. We were entitled to the Myovant Top-Up Shares pursuant to the Sumitomo Transaction, and this right to receive the Myovant Top-Up Shares was treated as contingent consideration upon sale of business and accounted for as a gain contingency. Refer to Note 11, "Discontinued Operations" of our audited financial statements for additional information. Liquidity and Capital Resources For the years ended March 31, 2023 and 2022, we incurred losses from continuing operations of approximately \$ 1.2 billion and \$ 924.1 million,

respectively. As of March 31, 2023, we had cash and cash equivalents of approximately \$ 1.7 billion and our accumulated deficit was approximately \$ 3.8 billion. Through our subsidiary Dermavant, we launched our first commercial product, VTAMA, following approval by the FDA in May 2022. We began generating product revenue, net from sales of VTAMA in the United States in May 2022. We also have generated revenue through license agreements as well as from subscription and service-based fees. Our short-term and long-term liquidity requirements as of March 31, 2023 included: • Contractual payments related to our long-term debt (see Note 9, “Long-Term Debt” of our audited financial statements); • obligations under our leases (see Note 15, “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; • certain commitments to Samsung Biologies 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 \$ 33.3 million; and • certain commitments to GSK pursuant to a commercial supply agreement entered between Dermavant and GSK. In conjunction with Dermavant’s entry into the GSK Agreement in 2018, Dermavant entered into a clinical supply agreement pursuant to which GSK would provide a supply of tapinarof and clinical product at an agreed-upon price during our clinical trials. In April 2019, Dermavant entered into a commercial supply agreement with GSK to continue to provide certain quantities of tapinarof and commercial product at agreed-upon minimum quantities and price. The commercial supply agreement commenced in April 2022 upon completion of certain quality and regulatory conditions. In July 2022, Dermavant and GSK amended the terms of the clinical supply and commercial supply agreements which released GSK of certain commitments to supply tapinarof and released Dermavant of certain commitments to purchase tapinarof in exchange for a supplementary fee. Other supply and purchase commitments under the agreements remain in effect. In addition, Dermavant and Thermo Fisher Scientific (“TFS”) entered into a Commercial Manufacturing and Supply Agreement for which TFS agreed to provide a supply of tapinarof to Dermavant at an agreed-upon price. The agreements discussed above require Dermavant to purchase certain quantities of inventory over a period of five years. The minimum purchase commitment related to these agreements is estimated to be approximately \$ 38.0 million. The above purchase commitments do not represent all of our anticipated purchases, but instead represent only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts. Additionally, we have certain payment obligations under various asset acquisition and license agreements. Under these agreements we are required to make milestone payments upon successful completion and achievement of certain development, regulatory and commercial milestones. The payment obligations under the asset acquisition and license agreements are contingent upon future events, such as our achievement of specified development, regulatory and commercial milestones, and the amount, timing, and likelihood of such payments are not known. We will also be required to make milestone payments and royalty payments in connection with the sale of products developed under these agreements. We 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 had cash, cash equivalents and restricted cash of approximately \$ 1.7 billion at March 31, 2023, which we expect to support cash runway into the second half of calendar year 2025. 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, together with Sumitomo, we completed the transactions contemplated by the transaction agreement by and between us and Sumitomo, dated as of October 31, 2019. In connection with the Sumitomo Transaction, we raised net proceeds of approximately \$ 999.2 million due to 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. In September 2022, we entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”) to sell our common shares having an aggregate offering price of up to \$ 400.0 million from time to time through an “at-the-market” equity offering program under which Cowen acts as our agent (the “ATM Facility”). As of March 31, 2023, we had \$ 400.0 million of remaining capacity available under the ATM Facility. In November 2022, we completed an underwritten primary and secondary public offering of 30,000,000 of our common shares at a price to the public of \$ 5.00 per share. Of these common shares, 20,000,000 were sold by us and 10,000,000 were sold by certain selling shareholders. Net proceeds to us were approximately \$ 94.7 million after deducting underwriting discounts and commissions and offering expenses. We did not receive any proceeds from the sale of common shares by the selling shareholders in the offering. In February 2023, we completed an underwritten public offering of 30,666,665 of our common shares (including 3,999,999 common shares issued and sold upon the full exercise of the underwriters’ option to purchase additional shares) at a price to the public of \$ 7.50 per share. Net proceeds to us were approximately \$ 216.9 million after deducting underwriting discounts and commissions and offering expenses. Sumitomo Transaction In December 2019, we closed the Sumitomo Transaction, including the transfer of our ownership interest in five Vants — Myovant, Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd. — to 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. In October 2022, Myovant entered into an agreement with Sumitomo, its majority shareholder, under which Sumitomo would acquire the remaining shares of Myovant not already owned by Sumitomo at a price of \$ 27.00 per share in a cash transaction (the “Myovant Transaction”). The acquisition of Myovant by Sumitomo was completed in March 2023. In connection with the closing of the Myovant Transaction, we received approximately \$ 114.6 million in March 2023 for the sale of the Myovant Top-Up Shares. Refer to Note 11, “Discontinued Operations” of our audited financial statements 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. 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. In October 2022, Immunovant completed an underwritten public offering of 12,500,000 shares of its common stock (including 416,667 shares of common stock purchased by us) at a price to the public of \$ 6.00 per share, for net proceeds to Immunovant of approximately \$ 70.2 million after deducting underwriting discounts and commissions and offering expenses.

Proteovant In December 2020, following Proteovant Sciences, Inc.’s (“Proteovant”) acquisition of Oneopia 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 with XYQ Luxeo S. A. R. L (“XYQ Luxeo”), as lender, and U. S. Bank National Association, as collateral agent, in May 2021, and Dermavant terminated the Hercules Loan Agreement. Following the approval of VTAMA by the FDA in May 2022, Dermavant received \$ 160.0 million in June 2022 pursuant to the terms of the RIPSA entered with XYQ Luxeo, NovaQuest Co-Investment Fund XVII, L. P., an affiliate of NovaQuest Capital Management, LLC, and MAM Tapir Lender, LLC, an affiliate of Marathon Asset Management, L. P., together with U. S. Bank National Association, as collateral agent. Under the terms of the RIPSA, Dermavant is obligated to pay royalties based on a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States, up to a cap of \$ 344.0 million, in exchange for the \$ 160.0 million in committed funding to be paid to Dermavant, conditioned on the approval of tapinarof by the FDA, which was achieved in May 2022. Dermavant used the RIPSA proceeds primarily for the milestone obligations to GSK, which was achieved upon FDA approval, and Welch Biotech Inc., which was achieved upon the first sale of VTAMA.

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. Our operating results, including our net losses, may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, our expenditures on other research and development activities and our commercialization efforts. We anticipate that our expenses will increase substantially as we:

- fund preclinical studies and clinical trials for our product candidates, which we are pursuing or may choose to pursue in the future;
- fund the manufacturing of drug substance and drug product of our product candidates in development;
- seek to identify, acquire, develop and commercialize additional product candidates;
- invest in activities related to the discovery of novel drugs and advancement of our internal programs;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- achieve milestones under our agreements with third parties that will require us to make substantial payments to those parties;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- build out our sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize VTAMA and any drug candidates for which we may obtain regulatory approval; and
- operate as a public company. We expect to continue to finance our cash needs through a combination of our cash on hand and future equity offerings, debt financings, sales of subsidiaries, and proceeds received from collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, licensing or similar arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be

favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.

**Cash Flows** The following table sets forth a summary of our cash flows for the years ended March 31, 2023 and 2022:

| Years Ended March 31, 2023 (in thousands)           | Years Ended March 31, 2022 |
|---|----------------------------|
| Net cash used in operating activities               | \$ (843, 393)              |
| Net cash (used in) provided by investing activities | \$ (44, 269)               |
| Net cash provided by financing activities           | \$ 303, 295                |

**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, 2023, cash used in operating activities increased by \$ 165.7 million to \$ 843.4 million compared to the year ended March 31, 2022. This increase was primarily driven by an increase in cash required to fund operations, particularly as a result of the progression of clinical programs, and to support the commercial launch of VTAMA.

**Investing Activities** Cash flow from investing activities includes cash used for milestone payments; purchase of property and equipment; and proceeds from sale of investment and other equity securities. For the year ended March 31, 2023, cash flow from investing activities changed by \$ 347.6 million to net cash used in investing activities of \$ 44.3 million from net cash provided by investing activities of \$ 303.3 million for the year ended March 31, 2022. This change in cash flow from investing activities is primarily related to \$ 320 million in cash we received as a result of the Datavant Merger during the year ended March 31, 2022. During the year ended March 31, 2023, cash used in investing activities was primarily driven by milestone payments made relating to VTAMA, which were partially offset by proceeds from the sale of the Myovant Top-Up Shares.

**Financing Activities** For the year ended March 31, 2023, cash provided by financing activities increased by \$ 192.7 million to \$ 499.5 million compared to the year ended March 31, 2022. During the year ended March 31, 2023, proceeds were generated by funding pursuant to the terms of the RIPSA following the approval of VTAMA by the FDA in May 2022 as well as net proceeds from the issuance of our common shares and common shares of our majority-owned subsidiary Immunovant. 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 Luxeo, 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.

**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.

**Product Revenue Reserves** We recognize revenue when the customer obtains control of the product, which occurs at a point in time, either upon shipment or delivery to the customer. Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established that result from (a) invoice discounts for prompt payment and specialty distributor and specialty pharmacy service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) performance rebates and administrative fees, (d) product returns and (e) costs of co-pay assistance programs for patients. We establish reserves based on these gross-to-net adjustments, which are based on amounts earned or to be claimed on the related sale and are classified as reductions of accounts receivable (if the amount is payable to the customer) or accrued expenses and other current liabilities (if the amount is payable to a party other than a customer). Where appropriate, we utilize the expected value method to determine the appropriate amount for estimates of variable consideration. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, our historical experience, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we adjust these estimates in the period such change in estimate becomes known, which could affect net product revenue and earnings in the period of the adjustment. We make significant estimates and judgments that materially affect our recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts may be submitted to us significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. We will adjust our estimates based on new information, including information regarding actual rebates, chargebacks and

discounts for our products, as it becomes available. The following table provides a summary of activity with respect to our sales allowances and accruals (in thousands):

|   | March 31, 2023 | March 31, 2022 |
|---|----------------|----------------|
| Sales return, rebate, and discounts balances, beginning of year | \$ —           | \$ —           |
| Reduction of gross sales  | (129, 717)     | —              |
| Cash payments   | 108, 923       | —              |
| Sales return, rebate, and discounts balances, end of year       | \$ (20, 794)   | \$ —           |

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 We did not adopt any material accounting pronouncements during the year ended March 31, 2023.

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 \$ 1.235 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 may continue to be a smaller reporting company as long as either (i) the market value of our common shares held by non-affiliates is less than \$ 250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenue is less than \$ 100 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than \$ 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.