UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2022

or

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

For the transition period from _____ to _____

Commission file number 001-37929

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Suite 1, 3rd Floor **11-12 St. James's Square** **London** **SW1Y 4LB** **United Kingdom**	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+44 (207) 400 3351**

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common Shares, $0.000017727 par value per share	MYOV	New York Stock Exchange

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

The aggregate market value of voting common shares held by non-affiliates of the registrant as of the end of the registrant's most recently completed second fiscal quarter ended September 30, 2021 was approximately $963,403,774 based on the last reported sale price of the registrant's common shares as reported on the New York Stock Exchange on September 30, 2021 of $22.44 per common share. Common shares held by our majority shareholder, Sumitovant Biopharma Ltd. and each officer and director have been excluded in that such persons, on such dates, may have been deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

The number of the registrant's common shares, $0.000017727 par value per share, outstanding on May 6, 2022, was 95,332,073.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2022 Annual General Meeting of Shareholders (the "2022 Proxy Statement") to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

MYOVANT SCIENCES LTD.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2022

TABLE OF CONTENTS

Information Relating to Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

The forward-looking statements appearing in a number of places throughout this Annual Report include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- our and our collaboration and commercialization partners' ability to successfully plan for and commercialize ORGOVYX®, MYFEMBREE®, and RYEQO®, as well as any product candidates, if approved;
- the success and anticipated timing of our clinical studies for our product candidates;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical and clinical studies;
- the anticipated designs of our future clinical studies;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain, regulatory approvals for our product candidates, including any decision the FDA may make regarding the supplemental New Drug Application ("sNDA") for MYFEMBREE for the management of moderate to severe pain associated with endometriosis;
- our ability to procure sufficient quantities of commercial relugolix drug substance and drug product from approved third party commercial manufacturing organizations ("CMOs");
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain and maintain reimbursement and coverage from government and private payers for our products if commercialized;
- the rate and degree of market acceptance and clinical utility of any approved products;
- our ability to initiate and continue relationships with third-party clinical research organizations and manufacturers and third-party logistics providers;
- our ability to quickly and efficiently identify and develop new product candidates;
- the impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related public health measures will have on our business operations, financial condition and results of operations;
- the impact of various social, political, economic, industry, inflationary or other market conditions in the U.S. and around the world (including wars and other forms of conflict such as the conflict in Ukraine);
- our ability to hire and retain our management and other key personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our products and product candidates;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- our ability to continue to fund our operations with the cash, cash equivalents, and marketable securities currently on hand, including our expectations for how long these capital resources will enable us to fund our operations;
- our expectations regarding potential future payments that we are eligible to receive from Pfizer Inc. ("Pfizer") under the Pfizer Collaboration and License Agreement, Gedeon Richter Plc. ("Richter") under the Richter Development and Commercialization Agreement, and Accord Healthcare, Ltd. ("Accord") under the Accord License Agreement;

- our ability to borrow under the Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma") Loan Agreement;
- third party collaboration partners' abilities to perform their obligations under our agreements with them;
- our ability to raise additional capital if needed, on acceptable terms to us;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, particularly in the section titled "Risk Factors" set forth in Part I. Item 1A. of this Annual Report, and in our other filings with the United States Securities and Exchange Commission ("SEC"). These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Trademarks and Certain Terms

In this Annual Report, references to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries on a consolidated basis, unless the context otherwise provides. All brand names or trademarks appearing in this Annual Report are the property of their respective owners.

This Annual Report may contain references to our proprietary intellectual property, including among others, trademarks for our products, ORGOVYX® and MYFEMBREE®. These trademarks and trade names are the property of Myovant or the property of our wholly-owned subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, our trademarks and trade names referred to in this Annual Report may appear without the ® or other symbols, but such references are not intended to indicate in any way that Myovant will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

Risk Factor Summary

Below is a summary of the material factors that make an investment in our common shares speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the heading "Risk Factors" in Item 1A of Part 1 of this Annual Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Item 1A of Part I of this Annual Report as part of your evaluation of an investment in our common shares.

Risks Related to Commercialization of Our Drug Products

- Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.
- Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.
- If we and our collaboration partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.

- Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.

- We face substantial competition in the commercialization of our approved drug products and our operating results will suffer if we fail to compete effectively.

- If we or our collaboration partners are found to have improperly promoted unapproved uses of our drug products, we may be subject to restrictions on the sale or marketing of our drug products and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

Risks Related to Our Financial Position and Capital Requirements

- If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.

- We may never achieve or maintain profitability.

Risks Related to Our Business Operations

- The terms of the Sumitomo Pharma Loan Agreement place restrictions on our operating and financial flexibility.

- We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products.

Risks Related to Clinical Development and Regulatory Approval

- Clinical studies are very expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.

- The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, our ability to generate net product revenue will be materially impaired.

- Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Risks Related to Our Dependence on Third Parties

- We are dependent upon our relationships with collaboration partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

- We are reliant on third parties to conduct, manage, and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

Risks Related to Our Intellectual Property

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

- If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

Risks Related to Our Being a Controlled Company

- We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

Part I.

Item 1. Business

Overview of our Business

We are a biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. by the U.S. Food and Drug Administration ("FDA") in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; and (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In April 2022, the EC approved ORGOVYX (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. In September 2021, the FDA accepted to review our supplemental New Drug Application ("sNDA") for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. On May 6, 2022, we and Pfizer announced that the FDA extended the Prescription Drug User Fee Act ("PDUFA") goal date for this sNDA to August 6, 2022. MYFEMBREE is being evaluated for contraceptive efficacy in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy. We are also developing MVT-602, an investigational oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from the upfront and milestone payments we have received from our collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S., and to a lesser extent from revenues generated from sales of product supply to Gedeon Richter Plc. ("Richter") as well as royalties on net sales of RYEQO in Richter's Territory.

Our majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma"), the name of which prior to April 1, 2022 was Sumitomo Dainippon Pharma Co., Ltd. As of March 31, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, own 50,041,181, or approximately 52.8%, of our outstanding common shares.

Our Strategy

Our business strategy is to maximize our current commercial brands through our and our partners' capabilities while expanding our pipeline of future growth opportunities. Our strategy for future growth is to leverage our core capabilities in science, partnerships, and transformative advocacy to create differentiated solutions in high unmet need areas within women's health and hormone-sensitive oncology. This includes the potential expansion of the existing labels for ORGOVYX and MYFEMBREE, the evaluation of relugolix and MVT-602 for other potential indications, and the addition of pipeline assets that align with our core expertise. The key elements of our strategy include the following:

- grow sales of ORGOVYX in the U.S. for the treatment of adult men with advanced prostate cancer;
- grow sales of MYFEMBREE in the U.S. for the management of heavy menstrual bleeding associated with uterine fibroids;

- seek regulatory approval and prepare for the potential commercialization of MYFEMBREE for the management of moderate to severe pain associated with endometriosis;
- seek regulatory approval to commercialize relugolix monotherapy tablet and relugolix combination tablet in other markets outside of the U.S. through our partnerships or on our own;
- leverage our collaboration with Pfizer Inc. ("Pfizer") to maximize the commercial potential of ORGOVYX and MYFEMBREE, while continuing to invest in the clinical development of relugolix for additional potential indications;
- leverage our collaboration with Richter to expand the commercialization of RYEQO for the treatment of uterine fibroids and to seek regulatory approval and commercialize RYEQO for endometriosis in certain territories outside of the U.S. and Canada;
- leverage our collaboration with Accord Healthcare, Ltd. ("Accord") to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX (relugolix 120 mg) in the European Economic Area, U.K., Switzerland, and Turkey;
- advance assessment and potential clinical development of MVT-602;
- expand our product portfolio and pipeline by expanding the existing labels for ORGOVYX and MYFEMBREE, evaluating relugolix potentially for other indications, and/or acquiring or in-licensing additional clinical-stage product candidates or commercial-stage products in a capital-efficient manner;
- deliver operational excellence while upholding the highest ethical and compliance standards in our business practices; and
- foster our values-based culture that embraces diversity and attract and retain highly skilled employees that value and contribute to the advancement of our patient-focused mission.

Relugolix in General

Relugolix is an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone ("GnRH") receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone ("LH") and follicle-stimulating hormone ("FSH")), thereby decreasing the downstream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men.

As a GnRH receptor antagonist, relugolix has a clinically-validated mechanism of action in each of our programs: advanced prostate cancer; heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and contraceptive efficacy. The direct and rapid action of relugolix on the pituitary-gonadal axis is distinct from approved luteinizing hormone-releasing hormone ("LHRH") agonists which are administered as depot injections and result in an initial surge in levels of gonadotropins, and estrogen and progesterone or testosterone, before resulting in pituitary desensitization and a fall in hormone levels over weeks. Approved LHRH agonist injections such as leuprolide acetate are used in women to treat the symptoms of uterine fibroids and endometriosis, but the adoption and duration of use is limited due to bone mineral density loss and vasomotor symptoms (such as hot flushes).

Our Approved Products and Product Candidates and the Market Opportunities

Advanced Prostate Cancer

Prostate cancer is a potentially lethal disease that starts in the prostate gland in men. Prostate cancer usually grows slowly and is confined, or localized, to the prostate gland. Cancer cells can grow beyond the prostate gland and spread to other tissues, also called metastasis.

On December 18, 2020, the FDA approved ORGOVYX for the treatment of adult patients with advanced prostate cancer. ORGOVYX, which was granted Priority Review by the FDA, is the first and only oral GnRH receptor antagonist for the treatment of men with advanced prostate cancer. The approval of ORGOVYX is based on efficacy and safety data from our Phase 3 HERO study of ORGOVYX in men with advanced prostate cancer. For the years ended March 31, 2022, and 2021, we generated net revenues from sales of ORGOVYX in the U.S. of $83.0 million and $3.6 million, respectively. Pursuant to the terms of our collaboration and license agreement by and between one of our subsidiaries and Pfizer (the " Pfizer Collaboration and License Agreement"), we collaborate with Pfizer to jointly develop and commercialize relugolix in oncology. We and Pfizer may conduct additional clinical studies to support the commercial potential of ORGOVYX.

On April 29, 2022, the EC approved ORGOVYX as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. This approval is applicable to all 27 EU member states plus Iceland, Norway, and Lichtenstein. We expect our commercialization partner, Accord, to launch ORGOVYX for this indication in Europe in the second half of calendar year 2022.

We expect to submit a New Drug Submission to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer in Canada in calendar year 2022.

Phase 3 HERO Study

In the Phase 3 HERO study, ORGOVYX met the primary endpoint and achieved sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% (95% confidence interval [CI]: 94.9-97.9) of men, compared with 88.8% (95% CI: 84.6-91.8) of men receiving leuprolide acetate injections, the current standard of care. ORGOVYX also achieved several key secondary endpoints compared to leuprolide acetate, including suppression of testosterone to castrate levels at Day 4 and Day 15 (56% versus 0% and 99% versus 12%, respectively) and profound suppression of testosterone (< 20 ng/dL) at Day 15 (78% versus 1%). ORGOVYX lowered prostate-specific antigen ("PSA"), on average, by 65% at Day 15 and by 83% at Day 29. In a substudy, 55% of men treated with ORGOVYX achieved normal testosterone levels (> 280 ng/dL) or returned to baseline within 90 days of treatment discontinuation. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group, were hot flush, musculoskeletal pain, fatigue, constipation, and mild to moderate diarrhea. In May 2020, efficacy and safety data from the Phase 3 HERO study were published online in the *New England Journal of Medicine*.

Advanced Prostate Cancer Market Opportunity

Prostate cancer is the second most prevalent form of cancer in men and the second leading cause of death due to cancer in men in the U.S. Approximately three million men diagnosed with prostate cancer are alive in the U.S., and approximately 250,000 men are newly diagnosed each year, according to the National Cancer Institute. Prostate cancer is the second most common cancer in the world and responsible for the fifth leading cause of cancer-related deaths. It is estimated that 1 in 9 men will be diagnosed with prostate cancer during their lifetime.

If prostate cancer is diagnosed at a stage where it is confined to the prostate gland and immediate surroundings, it is generally treated by surgical removal of the prostate gland (prostatectomy) or with radiation. Often, these procedures are successful in curing men of their disease. Men whose disease progresses after prostatectomy or radiation are said to have advanced prostate cancer. Advanced prostate cancer is defined as any of the following: PSA biochemical relapse following primary surgical or radiation therapy of curative intent; newly diagnosed metastatic prostate cancer; or advanced localized disease for which immediate radiation or surgical therapy is not indicated.

First-line treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapies ("ADT"), which are therapies that substantially reduce testosterone. This is because androgens, such as testosterone, promote the growth of cancerous prostate cells by binding to and activating the androgen receptor which, once activated, stimulates prostate cancer cell growth. ADT consisting of either medical castration or surgical castration (removal of the testes which produce testosterone) can be successful in delaying prostate cancer progression. As prostate cancer progresses, men remain on ADT while other therapies are added, typically until death.

The most commonly prescribed ADTs are LHRH agonists, such as long-acting leuprolide depot injections. LHRH agonists initially stimulate a testosterone surge, but with chronic stimulation of the LHRH receptors, the pituitary gland desensitizes and luteinizing hormone decreases with a resultant reduction in testosterone three to four weeks after the initiation of therapy. The initial stimulation of testosterone can cause an initial worsening of symptoms, or testosterone flare, and require additional medicines to manage its effects. LHRH agonists are often given as depot formulations, requiring injections every month, three months or six months, and testosterone may remain suppressed for weeks and months after cessation of therapy.

ORGOVYX provides rapid reduction of testosterone with no testosterone flare as seen with many other ADTs. Additionally, the testosterone reduction is profound and sustained as long as the patient remains on therapy and testosterone returns to normal levels quickly after stopping therapy. ORGOVYX is the only treatment option that offers these clinical benefits in an oral formulation. Over time, we believe that ORGOVYX has the potential to change the treatment paradigm and become a standard of care in the treatment of advanced prostate cancer.

Uterine Fibroids

Uterine fibroids, also known as uterine myomas or leiomyomas, are non-cancerous tumors that develop in the muscular wall of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth. Although uterine fibroids

are benign tumors, they may cause debilitating symptoms such as heavy and prolonged menstrual bleeding, heavy or painful periods, anemia, abdominal pain, backache, increased abdominal girth and bloating, urinary frequency or retention, constipation or painful defecation, pregnancy loss, painful intercourse and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment. For most women, uterine fibroids and associated symptoms resolve at menopause when estrogen and progesterone levels fall.

On May 26, 2021, the FDA approved MYFEMBREE as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months. The approval is supported by efficacy and safety data from our Phase 3 LIBERTY 1 and LIBERTY 2 studies, which were published in the *New England Journal of Medicine,* and the LIBERTY long-term extension study. For the year ended March 31, 2022, we generated net revenues from sales of MYFEMBREE in the U.S. of $6.4 million. Pursuant to the terms of the Pfizer Collaboration and License Agreement, we collaborate with Pfizer to jointly develop and commercialize relugolix in women's health.

On July 16, 2021, the EC, and on August 9, 2021, the MHRA, approved RYEQO as the first and only long-term, once-daily oral treatment in the EU and U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age with no limitation on its duration of use. The EC decision is valid in all 27 member states of the EU, as well as Iceland, Norway, and Liechtenstein. The approvals are based on the safety and efficacy data from the Phase 3 LIBERTY 1 and LIBERTY 2 studies, the LIBERTY long-term extension study, and supportive bone mineral density data from the LIBERTY randomized withdrawal study. Richter, our commercialization partner for RYEQO in Europe and certain other international markets, has launched RYEQO in 17 countries since these regulatory approvals.

We expect to submit a New Drug Submission to Health Canada seeking marketing approval for MYFEMBREE for heavy menstrual bleeding associated with uterine fibroids in Canada in calendar year 2022.

Phase 3 LIBERTY 1 and LIBERTY 2 Studies

The Phase 3 LIBERTY clinical program, which evaluated relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids, consisted of two multinational, replicate pivotal clinical studies. We enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products. Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 was the proportion of all women enrolled who achieved a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline during the last 35 days of the 24-week treatment period (responders) as measured by the alkaline hematin method. The secondary endpoints included the proportion of women who achieved amenorrhea (defined as no or negligible blood loss) during the last 35 days of treatment, reduction in pelvic pain, reduction in fibroid volume, reduction in uterine volume, percent change from baseline to week 24 in menstrual blood loss, increase in hemoglobin, and an assessment of the impact of therapy on quality-of-life. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry ("DXA"), was also assessed.

The Phase 3 LIBERTY studies each met the primary endpoint, with 72.1% and 71.2% of women in the MYFEMBREE groups achieving the responder criteria compared with 16.8% and 14.7% of women in the placebo groups at week 24, respectively (both $p < 0.0001$). Women receiving MYFEMBREE experienced reductions of 82.0% and 84.3% in menstrual blood loss from baselines, respectively (both $p < 0.0001$ compared to placebo). Adverse reactions occurring in at least 3% of women treated with MYFEMBREE and at a greater incidence than placebo were hot flush, abnormal uterine bleeding, alopecia (baldness), and decreased libido. There were no pregnancies reported in the MYFEMBREE groups in either study. The Phase 3 LIBERTY studies each met the same six key secondary endpoints with statistical significance compared to placebo, including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women received relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. Upon

completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, and to evaluate the need for maintenance therapy.

LIBERTY Long-Term Extension Study

On February 10, 2020, we announced positive one-year safety and efficacy data from the LIBERTY long-term extension study. In the primary endpoint analysis, 87.7% of women achieved the responder criteria, as defined above for LIBERTY 1 and LIBERTY 2. The one-year primary endpoint result in the LIBERTY open-label extension study demonstrated durability of the response observed in LIBERTY 1 and LIBERTY 2. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year.

Changes in bone mineral density through one year, as assessed by DXA every three months, were consistent with those in LIBERTY 1 and LIBERTY 2. The incidence of adverse events over one year was consistent with that observed in LIBERTY 1 and LIBERTY 2, with no new safety signals observed. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one year and more frequent than those reported in the placebo group after 6 months included only hot flash. There were no pregnancies reported in the relugolix combination therapy group.

In October 2020, we presented a poster at the American Society for Reproductive Medicine ("ASRM") 2020 Virtual Congress describing a validated exposure-response model simulating long-term effects of relugolix combination therapy on bone mineral density at the lumbar spine. Simulations from this model were well correlated with the effect of relugolix combination therapy observed in the Phase 3 LIBERTY program and projected maintenance of bone mineral density for at least three years.

Data from the LIBERTY long-term extension study were included in the original NDA submission for MYFEMBREE for the uterine fibroids indication.

LIBERTY Randomized Withdrawal Study

On March 24, 2021, we and Pfizer announced positive safety and efficacy data from the LIBERTY randomized withdrawal study. The LIBERTY randomized withdrawal study (n=229) was a Phase 3 double-blind, placebo-controlled study that enrolled eligible women who completed the LIBERTY long-term extension study. Eligibility criteria included meeting the responder criteria at one year. In this study, response was defined as sustained menstrual blood loss of less than 80 mL through week 76 or to week 104. Women were randomized at week 52 to once-daily relugolix combination therapy or placebo for a one-year double-blind treatment period. Women on placebo with relapse of heavy menstrual bleeding during the study were offered re-treatment with open-label relugolix combination therapy. This study, together with the LIBERTY 1, LIBERTY 2, and LIBERTY long-term extension study, was designed to provide data on the safety and efficacy of treatment with relugolix combination therapy for up to two years.

The LIBERTY randomized withdrawal study met its primary endpoint with 78.4% of women who continued on relugolix combination therapy achieving the sustained responder rate (menstrual blood loss < 80 mL) through week 76 compared with 15.1% of women who discontinued treatment and initiated placebo at week 52 ($p < 0.0001$). All three key secondary endpoints in the LIBERTY randomized withdrawal study were also achieved, including sustained responder rate at two years (week 104), time to relapse of heavy menstrual bleeding, and amenorrhea rate (all $p < 0.0001$). Through two years, 69.8% of women who continued on relugolix combination therapy remained responders. 88.3% of women who discontinued treatment at week 52 relapsed with heavy menstrual bleeding, with a median time of return to heavy menstrual bleeding of 5.9 weeks.

Bone mineral density was maintained through two years in the subset of women continuously treated with relugolix combination therapy (n=31). The incidence of adverse events over one additional year of treatment was consistent with those observed in prior studies, with no new safety signals observed. The most commonly reported adverse event in at least 10% of women treated with relugolix combination therapy was nasopharyngitis (inflammation of the nose and pharynx).

On March 29, 2022, one of our subsidiaries, Myovant Sciences GmbH ("MSG"), submitted an sNDA to the FDA that included the two-year data from the LIBERTY randomized withdrawal study.

Observational Bone Mineral Density Study

This prospective observational study was designed to characterize the longitudinal natural history of bone mineral density in premenopausal women with uterine fibroids or endometriosis over 52 weeks. A cohort of women (n=262) with documented uterine fibroids by imaging who were not receiving treatment with GnRH agonists or antagonists were enrolled contemporaneously from U.S. centers that participated in the LIBERTY studies. Bone mineral density was assessed by DXA at baseline, week 24 and week 52. Mean bone mineral density at the lumbar spine showed minimal changes over the 52-week

observational period (0% at week 24 and -0.41% at week 52) and did not appear to be influenced by race or body mass index. This study began in August 2018 and was completed in July 2020.

Uterine Fibroids Market Opportunity

We estimate that over 25% of women of reproductive age in the U.S., or approximately 19 million women, have uterine fibroids. Of those, approximately five million women are estimated to experience symptoms of uterine fibroids, approximately three million of whom are inadequately treated by current medical therapy and require further treatment. Heavy menstrual bleeding is defined as more than 80 mL in a cycle. It is the most common symptom of uterine fibroids and many of these women with heavy menstrual bleeding go undiagnosed.

The current approach to treating uterine fibroids includes both medical therapies and surgical options. The recommended treatment for a given patient is dependent on factors such as the patient's desire to become pregnant in the future, the importance of uterine preservation, symptom severity, and tumor characteristics. Medical options include oral contraceptives, GnRH antagonists, tranexamic acid, and LHRH agonists.

The current standard of care for the treatment of patients with mild symptoms includes the use of oral or other hormonal contraceptives or nonsteroidal anti-inflammatory drugs ("NSAIDs"), which are generally prescribed at the time of initial diagnosis. These therapeutic options, however, often do not provide sufficient relief to the many patients with more moderate-to-severe symptoms. These women require additional treatment to relieve excessive bleeding and pain. Tranexamic acid, an antifibrinolytic agent, is approved for use to treat heavy menstrual bleeding. LHRH agonists are used for short-term therapy and may involve low-dose estradiol and progestin hormonal combination therapy to mitigate the side effect of bone mineral density loss and reduce vasomotor symptoms generally associated with LHRH agonists. Recently the GnRH antagonist elagolix in combination with estradiol and a progestin, was approved for the management of heavy menstrual bleeding associated with uterine fibroids providing one new medical treatment option. However, treatment requires twice daily dosing and is associated with hot flashes and progressive bone loss. Other invasive procedures such as endometrial ablation and uterine artery embolization may also be tried. Surgical intervention, such as myomectomy or hysterectomy, are often used to treat the heavy bleeding and symptoms associated with uterine fibroids; however, these procedures may result in post-operative complications, complications with future pregnancy, or as is the case in hysterectomies, preclude the potential for future pregnancies. Even if a future pregnancy is not desired, many women prefer to avoid surgical intervention. However, heavy menstrual bleeding associated with uterine fibroids is a leading cause of hysterectomy, resulting in approximately 250,000 hysterectomies per year in the U.S. alone. The American College of Obstetricians and Gynecologists ("ACOG") updated their clinical management guidelines for the Management of Symptomatic Uterine Leiomyomas in June of 2021. These guidelines look to make recommendations based on good and consistent scientific evidence (Level A), limited or inconsistent scientific evidence (Level B) and those based primarily on consensus and expert opinion (Level C). They emphasize a patient-centered, shared decision-making approach when determining treatment. Oral contraceptives are given a Level C rating, versus newer oral GnRH therapies that are given a Level B rating for use for up to 2 years in abnormal uterine bleeding.

We believe that MYFEMBREE can potentially better meet the needs of women with uterine fibroids. Women receiving MYFEMBREE had a clinically meaningful reduction of menstrual blood loss of 84.3% over 24 weeks with approximately 50% reporting amenorrhea or absence of periods. The significant reduction of menstrual bleeding was associated with improvement of anemia in patients with anemia at baseline. Treatment was generally well tolerated with minimal changes in BMD with treatment. As the only one pill once a day available GnRH treatment, we believe MYFEMBREE has the potential to become a standard of care for the management of heavy menstrual bleeding associated with uterine fibroids potentially reducing the need for surgery or other invasive procedures.

Endometriosis

Endometriosis is an estrogen-dependent, inflammatory disease in which tissue similar to the lining of the uterus is found outside the uterine cavity. Endometriosis lesions commonly appear in the lower abdomen or pelvis or on ovaries, the bladder, or the colon. During the menstrual cycle, the lesions grow, differentiate, and shed into the abdomen, thereby inducing a cascade of inflammatory events. Endometriosis may cause debilitating symptoms such as dysmenorrhea (menstrual pain), non-menstrual pelvic pain, dyspareunia (painful intercourse), heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being. Pursuant to the terms of the Pfizer Collaboration and License Agreement, we collaborate with Pfizer to jointly develop and commercialize relugolix in women's health.

On September 9, 2021, we and our collaboration partner, Pfizer, announced that the FDA accepted for review an sNDA for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. On May 6, 2022, we and Pfizer announced that the FDA extended the PDUFA goal date to August 6, 2022 for the sNDA to allow time to review additional analyses related to bone mineral density submitted in response to the FDA's information request. No new clinical data was

requested by the FDA. The submission of the additional analyses has been determined by the FDA to constitute a Major Amendment to the sNDA, resulting in an extension of the PDUFA goal date.

We currently expect the European Medicines Agency regulatory submission for RYEQO for the treatment of endometriosis-associated pain in calendar year 2022. Richter, our commercialization partner for RYEQO in Europe and certain other international markets, will be the sponsor.

We expect to submit a New Drug Submission to Health Canada seeking marketing approval for MYFEMBREE for the treatment of endometriosis-associated pain in Canada in calendar year 2022.

Phase 3 SPIRIT 1 and SPIRIT 2 Studies

The Phase 3 SPIRIT clinical program, which evaluated relugolix combination therapy in women with pain associated with endometriosis, consisted of two multinational, replicate pivotal clinical studies. We enrolled 638 women in SPIRIT 1 and 623 women in SPIRIT 2. To be enrolled, women must have had a surgical diagnosis of endometriosis in the last 10 years and moderate-to-severe dysmenorrhea (menstrual pelvic pain) and non-menstrual pelvic pain. Each study randomized women 1:1:1 to one of three treatment arms. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

The co-primary efficacy endpoints for the SPIRIT 1 and SPIRIT 2 studies were the proportion of all women enrolled with reductions in both dysmenorrhea and non-menstrual pelvic pain, as assessed by an endometriosis-specific patient questionnaire based on the Numerical Rating Scale ("NRS") completed daily on an electronic patient diary, with no increase in background pain medication. The NRS is an 11-point scale with 0 representing "no pain" and 10 representing "the worst pain you can imagine." Secondary endpoints included additional questionnaires assessing functional changes associated with endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis, including opioid medications. Safety, including bone mineral density changes as measured by DXA, was also assessed.

SPIRIT 1

On June 23, 2020, we announced that SPIRIT 1 met its co-primary efficacy endpoints and all seven key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks.

Relugolix combination therapy achieved both co-primary endpoints by demonstrating clinically meaningful pain reductions for 74.5% of women with dysmenorrhea (menstrual pain) and 58.5% of women with non-menstrual pelvic pain, compared to 26.9% and 39.6% of women in the placebo group, respectively ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 73.3% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.3 (severe pain) to 1.8 (mild pain).

All seven key secondary endpoints measured at week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the EHP-30 pain domain, greater proportions of women not using analgesics (p-values < 0.0001), changes in mean non-menstrual pelvic pain ($p = 0.0002$), greater proportions of women not using opioids ($p = 0.0005$), and changes in mean dyspareunia (painful intercourse) ($p = 0.0149$).

The overall incidence of adverse events in the relugolix combination and placebo groups was similar (71.2% vs. 66.0%). In the relugolix combination therapy group, 3.8% of women had adverse events leading to discontinuation of treatment versus 1.9% in the placebo group. The only reported adverse events in at least 10% of women in the relugolix combination group were headache and hot flashes. There was one pregnancy in the relugolix combination group and three in the placebo group.

SPIRIT 2

On April 22, 2020, we announced that SPIRIT 2 met its co-primary efficacy endpoints and six key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks.

In the co-primary endpoint analysis, 75.2% of women achieved a clinically meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group ($p < 0.0001$). For non-menstrual pelvic pain, relugolix combination therapy achieved a clinically meaningful reduction in 66.0% of women versus 42.6% of women in the placebo group ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain).

Six key secondary endpoints measured at week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the EHP-30 pain domain, a greater proportion of women not using opioids (all p-values < 0.0001), changes in non-menstrual pelvic pain (p = 0.0012), and dyspareunia (painful intercourse) (p = 0.0489). An endpoint evaluating change in analgesic use did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was similar (80.6% vs. 75.0%). In the relugolix combination therapy group, 5.3% of women discontinued treatment early due to adverse events versus 3.9% in the placebo group. The most frequently reported adverse events, reported in at least 10% of women in the relugolix combination therapy group, were headache, nasopharyngitis, and hot flashes. There were three pregnancies in the relugolix combination therapy group and five in the placebo group.

SPIRIT Long-Term Extension Study

Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an active treatment long-term extension study in which all women received relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. A total of 802 women enrolled in the SPIRIT long-term extension study, all of whom received relugolix combination therapy regardless of their treatment assignment in SPIRIT 1 and SPIRIT 2.

On January 26, 2021, we and Pfizer announced positive one-year safety and efficacy data from the SPIRIT long-term extension study. In the primary endpoint analysis, 84.8% and 73.3% of women receiving relugolix combination therapy over one year achieved clinically meaningful pain reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. On average, women reported an 82.8% reduction on the 11-point Numerical Rating Scale (0-10) for dysmenorrhea from 7.4 (severe pain) to 1.3 (mild pain) over one year. Bone mineral density remained stable through week 52 in women treated with relugolix combination therapy after minimal, non-clinically meaningful bone loss through week 24. The incidence of adverse events over one year was consistent with that observed in the SPIRIT 1 and SPIRIT 2 studies, with no new safety signals observed. The most commonly reported adverse events in at least 10% of women treated with relugolix combination therapy were headache, nasopharyngitis, and hot flashes. There was one pregnancy reported in the relugolix combination therapy group (n=278).

In the primary endpoint analysis for the two-year extension study, 84.8% and 75.8% of women receiving relugolix combination therapy for up to two years achieved clinically meaningful pain reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. The incidence of adverse events over two years was consistent with that observed in the SPIRIT 1 and SPIRIT 2 studies and the first 28 weeks of the long- term extension study, with no new safety signals observed. The most commonly reported adverse events with relugolix combination therapy were headache, nasopharyngitis, and hot flashes. There were two additional pregnancies reported in the relugolix combination therapy group (n=278) during the second year of the long- term extension study. Bone mineral density remained stable through week 104 in women treated with relugolix combination therapy after minimal, non-clinically meaningful bone loss through week 24. We expect to present two-year data from the SPIRIT long-term extension study at a scientific conference in mid-calendar year 2022.

Observational Bone Mineral Density Study

This prospective observational study was designed to characterize the longitudinal natural history of bone mineral density in premenopausal women with uterine fibroids or endometriosis over 52 weeks. A cohort of women (n=452) with documented endometriosis by surgery who were not receiving treatment with GnRH agonists or antagonists were enrolled contemporaneously from U.S. centers that participated in the SPIRIT studies. Bone mineral density was assessed by DXA at baseline, week 24 and week 52. Mean bone mineral density at the lumbar spine showed minimal changes over the 52-week observational period (0.35% at week 24 and 0.53% at week 52) and did not appear to be influenced by race or body mass index. This study began in August 2018 and was completed in July 2020.

Endometriosis Market Opportunity

We estimate that endometriosis affects approximately 10% of women of reproductive age and, in the U.S., can take approximately 4-11 years from the onset of symptoms to accurately diagnose, often leading to unnecessary or inappropriate treatment. We estimate that approximately six million women in the U.S. suffer from symptomatic endometriosis, approximately one million of whom are inadequately treated by oral contraceptives and require additional treatment. We estimate that three in four women with endometriosis experience debilitating symptoms. In addition, approximately 100,000 endometriosis-related hysterectomies are performed each year in the U.S., although hysterectomy is not a cure for endometriosis and pain associated with endometriosis will not necessarily subside following hysterectomy.

Standard treatment options for endometriosis include medical therapies and surgery. Initial treatment usually involves over-the-counter pain medications, including NSAIDs, because pain is the primary symptom. Hormonal contraceptives are also commonly used. In more severe cases, LHRH agonists such as leuprolide are used for short-term treatment and may involve hormonal add-back therapy with an estrogen and/or a progestin. The FDA has approved Lupaneta Pack (leuprolide administered with norethindrone acetate (5 mg)) to treat pain associated with endometriosis while lowering the side effect of bone mineral density loss and reducing vasomotor symptoms use longer than one year is not recommended. The GnRH antagonist, elagolix, is approved for the management of moderate to severe pain associated with endometriosis. The low dose of elagolix is associated with limited efficacy but is generally well tolerated and can be used for up to two years. The high dose is more efficacious but is associated with a high incidence of hot flashes and progressive loss of bone density and, therefore, is only recommended for six months. For many patients, surgical intervention, typically laparoscopy with ablation or resection of endometriotic lesions, is ultimately undertaken to relieve pain, and opioid medications are frequently needed to control pain both before and after surgery. After treatment with hormonal therapy or laparoscopic procedures, recurrence of endometriosis and related symptoms is common, resulting in repeated procedures for many women.

We believe MYFEMBREE, if approved for endometriosis, could potentially provide a medical treatment option for women with pain associated with endometriosis that reduces both menstrual pain (dysmenorrhea) and non-menstrual pelvic pain, pain with intercourse (dyspareunia) leading to improvements of function and other measures of quality of life. This may reduce the need for repeated surgeries that many women with endometriosis undergo and to avoid the risks associated with multiple surgical interventions. If approved, MYFEMBREE would offer women with endometriosis effective management of their endometriosis-associated pain in a convenient one pill once a day therapy and allowing them to potentially delay or avoid surgery.

Prevention of Pregnancy

Uterine fibroids and endometriosis occur in premenopausal women who may desire to prevent pregnancy while receiving treatment for their heavy menstrual bleeding or pelvic pain. However, when using medical options like LHRH agonists or GnRH antagonists, the use of effective contraceptives such as combined hormonal contraceptives is not recommended. Their use may reduce the efficacy of treatment with LHRH agonists or GnRH antagonists and, in some cases, the efficacy of the contraceptives may be reduced, and the concomitant use of these therapies may increase the risk of severe and serious adverse events including thromboembolic events.

In April 2020, we announced results from a Phase 1 single-arm, open-label ovulation inhibition study to assess the effects of relugolix combination therapy on ovulation inhibition, per the Hoogland-Skouby assessment scale (score < 5). In 67 healthy women over an 84-day treatment period (three cycles), relugolix combination therapy achieved 100% ovulation inhibition and was generally well tolerated. Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment, with an average time to ovulation of 23.5 days. Data from this study were presented at the ASRM 2020 Virtual Congress. The findings of the Phase 1 study demonstrated that relugolix combination therapy inhibited ovulation study participants and provides the basis for our Phase 3 SERENE study.

Phase 3 SERENE Study

We are enrolling patients in our Phase 3 SERENE study evaluating MYFEMBREE for the prevention of pregnancy. The enrollment target in the SERENE study is 1,020 patients who are 18 to 50 years of age and at risk for pregnancy, who have a confirmed diagnosis of uterine fibroids or endometriosis. The primary efficacy endpoint is the at-risk Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. On-treatment pregnancies are pregnancies with an estimated conception date between the first day of study intervention intake up to and including seven days after the last intake of study medication. In May 2021, the FDA informed us that they placed a partial clinical hold on the Phase 3 SERENE study, pending certain protocol modifications. In August 2021, the FDA informed us that the partial clinical hold for the Phase 3 SERENE study was lifted following study protocol amendments. The primary analysis of the study, prevention of pregnancy, remains unchanged, but now the SERENE study will only evaluate women with a confirmed diagnosis of uterine fibroids or endometriosis. Bone mineral density monitoring will occur throughout the treatment period as well as after treatment is discontinued to gain additional insights into bone health, which will augment the safety profile observed in the LIBERTY and SPIRIT programs. The enrollment target was increased to 1,020 patients who are 18 to 50 years of age and at risk for pregnancy, enhancing the power of the study. Patient screening with this updated protocol began in September 2021, with initial patients dosed in October 2021. Women will receive once-daily MYFEMBREE for 13 28-day at-risk cycles. Safety data will also be collected during the study.

MVT-602

As part of our license agreement with Takeda, we acquired the worldwide rights to MVT-602, our second product candidate, which previously had been evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin,

the ligand, is a naturally occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization ("IVF"). Approximately 1.5 million assisted reproduction cycles are performed each year worldwide. Further, approximately 25% of women suffering from infertility have problems achieving ovulation, including the inability to produce fully matured eggs or the failure to ovulate, most commonly resulting from hormonal dysfunction in the GnRH-luteinizing hormone/follicle-stimulating hormone axis. We believe MVT-602 has the potential to be a safer alternative to human chorionic gonadotropin as a part of assisted reproduction for the treatment of female infertility.

We believe that MVT-602, an analog of the naturally-occurring kisspeptin peptide in humans, may mimic natural physiology by inducing a luteinizing hormone surge during IVF and other assisted reproductive technologies, enhancing the likelihood of successful egg maturation and ovulation at the right time without the serious side effect of ovarian hyperstimulation syndrome ("OHSS"). While assisted reproductive technologies are effective, typically resulting in pregnancy in 20% to 35% of patients, the standard procedure has remained largely unchanged since inception and has potentially serious side effects. The most serious side effect of assisted reproduction is OHSS. Severe OHSS has been reported to occur in up to 2% of the general assisted reproduction population, and in up to 20% of patients at high-risk for developing OHSS, including women with polycystic ovarian syndrome. OHSS is thought to occur as a result of the nonphysiologic elevations in luteinizing hormone that occur as a result of egg maturation triggered with human chorionic gonadotropin and to a lesser extent the GnRH receptor agonists. Symptoms can range from abdominal pain and bloating in milder cases to rapid weight gain, severe abdominal pain, nausea and vomiting, blood clots, decreased urination, kidney failure, and shortness of breath.

By acting upstream in the GnRH-axis to promote the release of physiologically normal levels of key hormones in the assisted reproduction cycle such as luteinizing hormone, kisspeptin agonists, such as MVT-602, may have the potential to trigger egg maturation without causing OHSS. A recently published investigator-sponsored study, where a native kisspeptin peptide (specifically, kisspeptin 54) was used in place of human chorionic gonadotropin as the egg-maturation trigger in the assisted reproduction cycle, showed that none of the 60 high-risk patients developed moderate-to-severe OHSS and resulted in a live birth rate of up to 65.1% at the maximally efficacious dose tested. These results validate the potential use of kisspeptin analogs as an alternative to the standard egg maturation trigger in assisted reproduction protocols. To our knowledge, MVT-602 is the only kisspeptin-1 receptor agonist in clinical development and thus has the potential to become a safe alternative egg-maturation trigger in this space.

In October 2018, we presented data from a Phase 1 study of MVT-602 at the ASRM Annual Congress. Results of the study showed that administration of MVT-602 in healthy premenopausal women in the follicular phase produced a dose-related increase in LH concentrations and expected effects on FSH and estradiol. A total of 24 women were randomized to one of three MVT-602 dose groups (0.3 μg, 1 μg or 3 μg) and then subsequently randomized within the assigned group to receive a single subcutaneous dose of MVT-602 or placebo in a 3:1 ratio. Results showed that administration of single subcutaneous doses of MVT-602 demonstrated dose-related increases in LH concentrations and expected post-dose increases in FSH and estradiol concentrations, with little effect observed on progesterone as expected. No serious adverse events were reported, and no subject discontinued from the study due to an adverse event. Adverse events were similar between the placebo and MVT-602 groups with no apparent dose-related effects.

Further assessment of the exposure-response profile of MVT-602 was conducted in a Phase 2a study during the pre-ovulatory phase in 75 fertile women following a minimal controlled ovarian stimulation protocol. After ovarian stimulation, women were randomized to one of four MVT-602 dose groups (0.1 μg, 0.3 μg, 1 μg or 3 μg), to triptorelin, 0.2 mg, or to placebo. Top-line results from this Phase 2a study were presented at the European Society of Human Reproduction and Embryology in Vienna, Austria in June 2019. The study demonstrated that MVT-602 was generally well-tolerated and produced the desired LH surge associated with high and dose-dependent rates of ovulation in healthy women following a minimal controlled ovarian stimulation protocol. This study provides information for dose selection for a future study of MVT-602 in infertile women seeking pregnancy.

Our Key Agreements

Collaborations and License Agreements

We have collaborations and license agreements with leading pharmaceutical companies for the commercialization and further development of relugolix. Our agreements with Pfizer, Richter, and Accord are described below.

Pfizer Collaboration and License Agreement

On December 26, 2020, one of our subsidiaries, MSG, and Pfizer, entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). In addition, Pfizer also received an option to acquire exclusive commercialization and development rights to relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries. Pfizer notified us on October 22, 2021, of its decision to decline this option.

In the Co-Promotion Territory, we and Pfizer equally share profits and certain expenses. We remain responsible for regulatory interactions and drug supply and continue to lead clinical development for MYFEMBREE in the women's health indications, while development for ORGOVYX is shared equally among the parties.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, we received an upfront payment of $650.0 million in December 2020, and are eligible to receive up to $3.8 billion of milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for MYFEMBREE in uterine fibroids and endometriosis ($200.0 million in the aggregate), and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. In July 2021, we received a $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, we have and will continue to bear Pfizer's share of Allowable Expenses, up to a maximum of $100.0 million for calendar year 2021 and up to a maximum of $50.0 million for calendar year 2022. Any unused portion will carry over into the subsequent calendar years until we have assumed in aggregate $150.0 million of Pfizer's share of the Allowable Expenses.

The term of the Pfizer Collaboration and License Agreement continues until no products are sold and all development activities have terminated in the Co-Promotion Territory. The Pfizer Collaboration and License Agreement may be terminated early by either party for the uncured material breach of the other party or for bankruptcy or other insolvency proceeding of the other party. In addition, Pfizer has certain other termination rights and may terminate the Pfizer Collaboration and License Agreement early upon providing written notice to us pursuant to the terms of the Pfizer Collaboration and License Agreement.

Richter Development and Commercialization Agreement

On March 30, 2020, one of our subsidiaries, MSG, entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand (the "Richter Development and Commercialization Agreement"). Under the terms of the Richter Development and Commercialization Agreement, we received an upfront payment of $40.0 million on March 31, 2020, and are eligible to receive up to $40.0 million in regulatory milestone payments (of which $25.0 million has been received), $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval.

Under the terms of the Richter Development and Commercialization Agreement, we continue to lead global development of relugolix combination tablet. We have also agreed to assist Richter in transferring manufacturing technology from our contract manufacturing organizations to Richter to enable Richter to manufacture relugolix combination tablet. We have agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to our agreements with our contract manufacturing organizations. Richter is responsible for all local clinical development, manufacturing, and all commercialization activities for its territories. We have also granted Richter an option to collaborate with us on relugolix combination tablet for future indications in women's health other than fertility.

The term of the Richter Development and Commercialization Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Richter Development and Commercialization Agreement) for the respective product in a country in the Richter Territory. The Richter Development and Commercialization Agreement may be terminated in its entirety or on a country-by-country basis by mutual consent of the parties, or by either party for the uncured material breach of the other party, for bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Richter Development and Commercialization Agreement.

Accord License Agreement

On May 5, 2022, one of our subsidiaries, MSG, entered into an exclusive license agreement (the "Accord License Agreement") with Accord and Intas Pharmaceuticals, Ltd., parent entity of Accord, for Accord to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX® (relugolix 120 mg) in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa, and India.

Under the terms of the Accord License Agreement, we are entitled to receive an upfront payment of $50.0 million, which we expect to receive in the three months ending June 30, 2022. We are also eligible to receive up to $90.5 million in commercial launch, sales-based, and other milestones. In addition, we are eligible to receive tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's territories.

Under the terms of the Accord License Agreement, we retain all rights to relugolix in the U.S., with our collaboration partner, Pfizer, as well as rights to relugolix in other therapeutic areas outside of prostate cancer, uterine fibroids, and endometriosis in Europe. We will continue to lead the global development of relugolix and provide initial product supply to Accord. Accord will be responsible for certain local clinical development and all commercialization for its territories, and has the option to manufacture relugolix in the future.

The term of the Accord License Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Accord License Agreement). The Accord License Agreement may be terminated in its entirety or on a country-by-country basis, by either party for the uncured material breach or bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Accord License Agreement.

Related Party Agreements

Our majority shareholder is Sumitovant, a wholly-owned subsidiary of Sumitomo Pharma. We have agreements with Sumitovant, Sumitomo Pharma, and their affiliates, including Sunovion Pharmaceuticals Inc. ("Sunovion"), a subsidiary of Sumitomo Pharma. The agreements that are material to us are described below.

Sumitomo Pharma Loan Agreement

On December 27, 2019, we and one of our subsidiaries, MSG, entered into a loan agreement with Sumitomo Pharma (the "Sumitomo Pharma Loan Agreement"). Pursuant to the Sumitomo Pharma Loan Agreement, Sumitomo Pharma agreed to make revolving loans to us in the aggregate principal amount of up to $400.0 million, of which $358.7 million was outstanding as of March 31, 2022. Funds may be drawn down by us once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024, or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the Sumitomo Pharma Loan Agreement. In addition, if Sumitomo Pharma fails to own at least a majority of our outstanding common shares, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to us, and in which case we would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Interest is due and payable quarterly. Loans under the Sumitomo Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Pharma Loan Agreement bear interest at a variable rate per annum equal to 3-month London Interbank Offered Rate ("LIBOR") plus a margin of 3% payable on the last day of each calendar quarter. Publication of 3-month LIBOR is currently expected to be discontinued on June 30, 2023. In the event that 3-month LIBOR becomes unavailable, we and Sumitomo Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. Our obligations under the Sumitomo Pharma Loan Agreement are fully and unconditionally guaranteed by us and our subsidiaries. The loans and other obligations are senior unsecured obligations of us, MSG, and subsidiary guarantees. The Sumitomo Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries and certain breaches by us under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5% will apply to the outstanding principal amount of the loans, Sumitomo Pharma may terminate its obligations to make loans to us and declare the principal amount of loans to become immediately due and payable, and Sumitomo Pharma may take such

other actions as set forth in the Sumitomo Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Pharma to make loans to us would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Pharma to maintain the loans under the Sumitomo Pharma Loan Agreement or within 30 days of a change of control with respect to us, we would be required to repay the outstanding principal amount of the loans.

Investor Rights Agreement

On December 27, 2019, we entered into an Investor Rights Agreement with Sumitomo Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, we agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, we agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to our books, records, facilities and employees during our normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for our minority shareholders for so long as Sumitomo Pharma or certain of its affiliates beneficially owns more than 50% of our common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of our board of directors or in the same proportion as the shareholders not affiliated with Sumitovant vote their shares; (ii) a requirement that the audit committee of our board of directors be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Pharma or certain of its affiliates that would increase Sumitomo Pharma's beneficial ownership to over 60% of the outstanding voting power of us must be approved by our audit committee (if occurring prior to December 27, 2022) and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares held by such shareholders; and (iv) a requirement that any related person transactions between Sumitomo Pharma or certain of its affiliates and us must be approved by our audit committee.

Pursuant to the Investor Rights Agreement, we also agreed that at all times that Sumitomo Pharma beneficially owns more than 50% of our common shares, Sumitomo Pharma, by purchasing common shares in the open market or from us in certain specified circumstances, will have the right to maintain its percentage ownership in our common shares in the event of a financing event or acquisition event conducted by us, or specified other events, subject to specific conditions.

Market Access Services Agreement

On August 1, 2020, one of our subsidiaries, MSG, entered into the Market Access Services Agreement, as amended, ("Market Access Services Agreement") with Sunovion. Pursuant to the Market Access Services Agreement, among other things, Sunovion agreed to provide to MSG certain market access services with respect to the distribution and sale of ORGOVYX ("Prostate Cancer Product") and MYFEMBREE ("Women's Health Product," and collectively with Prostate Cancer Product, the "Products", and each a "Product"), including, among other things: (i) adding the Products to Sunovion's agreements with its third party logistics providers; (ii) adding the Women's Health Product to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks and negotiating rates for the Products with certain market access customers; (iii) providing order-to-cash services; (iv) providing certain employees to provide market access account director services; (v) performing activities required in connection with supporting and maintaining contracts between us and market access customers for the coverage, purchase, or dispensing of the Products; (vi) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to the Products; (vii) providing MSG with price reporting metrics and other information required to allow us to comply with applicable government price reporting requirements; (viii) coordinating with MSG and any applicable wholesalers and distributors to address any recalls, investigations, or product holds; (ix) configuring, or causing to be configured, the appropriate software systems to enable Sunovion to perform its obligations under the Market Access Services Agreement; and (x) providing training and certain other ancillary support services to facilitate the foregoing. Pursuant to this agreement, Sunovion will also provide certain services to us to enable us to comply with our obligations under the State Transparency Laws.

MSG, in turn, appointed Sunovion as the exclusive distributor of the Women's Health Product and a non-exclusive distributor of the Prostate Cancer Product, each in the United States, including all of its territories and possessions.

In order to facilitate Sunovion's provision of these services, MSG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by MSG, solely for Sunovion's use in connection with its performance of the contemplated services; (ii) provide Sunovion periodic reports of sales projections and estimated volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which the Products will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of MSG's quality systems solely

related, as reasonably determined by us, to Sunovion's performance of certain regulatory services, at Sunovion's costs; and (v) promptly notify Sunovion in the event relugolix is recalled.

As consideration for the services, MSG has paid and will continue to pay Sunovion an agreed-upon monthly service charge for each of the first two years of the Market Access Services Agreement term and any agreed regulatory and training service charges. After the second year of the Market Access Services Agreement term, the monthly service charges will be determined by the parties. In addition, MSG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services, and (y) establish an escrow fund for use by Sunovion to manage payments for rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent not to renew the Market Access Services Agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the Market Access Services Agreement prior to the end of its term in the event of an uncured material breach by the other party, if there are certain changes of law, or if such other party becomes insolvent or undergoes a change of control. MSG may also terminate the Market Access Services Agreement with respect to one or both Products if Sunovion fails to satisfy certain market access milestones or for convenience upon payment of a break-up fee.

Other Agreements

Takeda License Agreement

On April 29, 2016, we entered into a License Agreement with Takeda (as subsequently amended, the "Takeda License Agreement") pursuant to which Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited ("Takeda Limited"), the originator of relugolix, granted to us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. The territory for our exclusive license for relugolix covers all countries worldwide, except that Takeda retains exclusive rights to Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam (including, in each case, the territories and possession of each of the foregoing), which we collectively refer to as the Takeda Territory. Takeda has granted us a nonexclusive license in the Takeda Territory to manufacture relugolix and to conduct development of relugolix for prostate cancer solely for the purpose of developing, manufacturing and commercializing relugolix in our territory. The territory for our exclusive license for MVT-602 covers all countries worldwide. Our license includes a right of reference to regulatory materials related to relugolix and MVT-602 controlled by Takeda. On May 31, 2018, Takeda announced that they entered into a licensing agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis in Japan.

Under the Takeda License Agreement, we granted to Takeda an exclusive, royalty-bearing license in the Takeda Territory under certain patents and other intellectual property controlled by us to develop and commercialize relugolix and products containing relugolix for all human diseases and conditions, subject to our nonexclusive rights to conduct development and manufacturing as described above. We also granted to Takeda a nonexclusive license in our territory to manufacture relugolix and MVT-602; and to conduct development of relugolix for uterine fibroids and endometriosis solely for the purpose of developing, manufacturing and commercializing relugolix in the Takeda Territory. Takeda's license includes a right of reference to regulatory materials controlled by us. If Takeda determines not to seek regulatory approval for or to commercialize relugolix in any country in the Takeda Territory, then we have a right of first negotiation to acquire the rights to seek regulatory approval and commercialize relugolix in such country.

We are solely responsible, at our expense, for all activities related to the development of relugolix and MVT-602 in our territory and all activities related to the development of relugolix through the receipt of regulatory approval for prostate cancer in certain countries in the Takeda Territory. Pursuant to the terms of the Takeda License Agreement, we are required to use commercially reasonable efforts to develop and obtain regulatory approval of relugolix for the treatment, prevention, cure or control of symptoms associated with uterine fibroids or endometriosis and MVT-602 in our territory, as well as to develop and obtain regulatory approval of relugolix for prostate cancer in Japan and the U.S. We are solely responsible, at our expense, for all activities related to the commercialization of relugolix and MVT-602 in our territory and must use commercially reasonable efforts to do so in each country in our territory in which we obtain regulatory approval. Takeda is solely responsible, at its expense, for all activities related to the commercialization of relugolix in the Takeda Territory, and must use diligent efforts to commercialize relugolix for prostate cancer in the Takeda Territory following receipt of regulatory approval.

Under the Takeda License Agreement, we will pay Takeda a fixed, high single-digit royalty on net sales of certain relugolix products, a low single-digit royalty on net sales of certain other relugolix products, and a high single-digit royalty on net sales

of MVT-602 products in our territory, all subject to certain agreed reductions. Takeda will pay us a high single-digit royalty on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones. We have also licensed additional patents and patent applications from Takeda directed to other oligopeptides that target the same pathway as MVT-602.

The Takeda License Agreement will expire, on a product-by-product and country-by-country basis, on the expiration of the royalty payment term described above for such product in such country. Either party may terminate the Takeda License Agreement for the other party's uncured material breach, challenge to the patents licensed under the Takeda License Agreement, or insolvency. Takeda may terminate the Takeda License Agreement with respect to a compound if we cease development or commercialization of such compound. We may terminate the agreement at will, in our sole discretion, in its entirety, or with respect to relugolix for prostate cancer or both endometriosis and uterine fibroids, or on a compound by compound basis for all fields, upon prior notice, with the notice period depending on the compound and field to be terminated and the regulatory status at the time that notice of termination is given. We may also terminate the agreement with respect to a compound for safety reasons or lack of commercial viability. If the agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by us for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then we must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed cap, or complete ourselves the conduct of any clinical studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at our cost and expense. If we reimburse Takeda for such costs, then under certain circumstances we may be later reimbursed by Takeda through a royalty on sales of the terminated relugolix product.

Takeda Supply Agreements

In June 2016, we and one of Takeda's affiliates, Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited supplied us with, and we obtained from Takeda Limited, all of our requirements for relugolix drug substance and drug product that were used under our development plans.

On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which Takeda agreed to supply us with and we agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications. For relugolix drug substance manufactured or delivered on or after December 31, 2019, we will pay Takeda a price per kilogram of relugolix drug substance to be agreed upon between the parties at the beginning of each fiscal year. Takeda has also assisted with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of one of our subsidiaries, MSG.

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018, and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement will automatically renew for successive one-year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

The Takeda Commercial Supply Agreement also includes customary provisions relating to, among others, delivery, inspection procedures, warranties, quality management, storage, handling and transport, intellectual property, confidentiality and indemnification.

Excella Commercial Manufacturing and Supply Agreement

On April 4, 2019, one of our subsidiaries, MSG, entered into a Commercial Manufacturing and Supply Agreement with Excella GmbH & Co. KG ("Excella") pursuant to which Excella agreed to manufacture and supply us with certain commercial relugolix active pharmaceutical ingredient ("API"). Subject to and under the terms and conditions of this agreement, Excella shall not develop, manufacture or supply any relugolix API or regulatory starting material, or any product containing relugolix, for or to any third party without our written consent.

Commercialization of our Approved Products

Our fully integrated commercial organization consists of sales, marketing, market access, and commercial operations functions. In the U.S., our sales teams market ORGOVYX primarily to urologists and oncologists and MYFEMBREE primarily to gynecology practices, as well as to other healthcare professionals. In the U.S., our sales and marketing efforts are supported by Pfizer pursuant to the terms of the Pfizer Collaboration and License Agreement, in which we collaborate to jointly develop and commercialize relugolix in oncology and women's health.

In addition to using customary pharmaceutical company practices, we, and Pfizer, have also adopted digital marketing technologies to engage with customers. The use of digital marketing technologies increased as a result of the COVID-19 pandemic, which required us, and Pfizer, to shift from customary in-person to primarily telephonic and virtual interactions with healthcare professionals. For a more detailed discussion of the impact of the COVID-19 pandemic and our risk mitigation efforts, see "Management's Discussion and Analysis of Financial Condition and Results of Operations— Effects of the COVID-19 Pandemic on our Business" in Part II, Item 7 of this Annual Report.

Our approved products, ORGOVYX and MYFEMBREE, are sold in the U.S. principally through wholesale and specialty distribution and pharmacy channels. These customers subsequently resell our products to healthcare providers and patients. To facilitate our commercial activities in the U.S., we also engage with various other third parties such as advertising agencies, market research firms and vendors providing other sales-support related services as needed, including digital marketing and other promotional activities.

To help ensure that all eligible patients in the U.S. have appropriate access to ORGOVYX and MYFEMBREE, we have established comprehensive reimbursement and support programs. Under these programs, we provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs and provide free drug to uninsured or under-insured patients who meet certain criteria. In addition, our programs provide comprehensive reimbursement support services, such as prior authorization support.

Pursuant to the Richter Development and Commercialization Agreement, we granted Richter an exclusive license to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Since RYEQO's approvals in the EU and U.K. for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, Richter has launched RYEQO in 17 countries.

Pursuant to the Accord License Agreement, we granted Accord an exclusive license to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX in the European Economic Area, U.K., Switzerland, and Turkey. Accord expects to launch ORGOVYX for this indication in Europe in the second half of calendar year 2022.

Manufacturing and Product Supply

We do not own or operate, nor do we expect to own or operate, facilities for drug substance and drug product manufacturing, storage and distribution, or testing of our product or product candidates. We contract with third parties for these activities and expect to continue to do so in the future. We have personnel with extensive technical, manufacturing, analytical and quality experience and strong project management discipline to oversee activities performed by third-party contract manufacturing organizations and testing activities performed by other third parties, and to compile manufacturing and quality information for our regulatory submissions.

Manufacturing of any product or product candidate is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. We expect that all of our contract manufacturing organizations will manufacture relugolix and MVT-602 under current good manufacturing practice ("cGMP") conditions, which set forth the regulatory standards for the production of pharmaceuticals to be used in humans. However, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and other regulations and laws for the manufacture of our product 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 foreign regulatory authorities, they may not be able to secure or maintain regulatory approvals for their manufacturing facilities and any applications that we submit to the FDA or other regulatory authorities that list those manufacturing facilities may be negatively affected.

If there are delays in initiating new relationships with one or more other third-party manufacturers for MVT-602, or if there are delays in completing technology transfer to any of these manufacturers, or if any of our third-party manufacturers experience

adverse developments, including with respect to adverse findings during inspections and/or the COVID-19 pandemic, we could experience delays in our future development and commercialization efforts.

Competition

The pharmaceutical and biopharmaceutical industries are highly competitive and require an ongoing, extensive search for technological innovation. These industries are characterized by rapid and significant technological advancements, intense competition, and a strong emphasis on proprietary products. While we believe that our products, product candidates, knowledge, experience, and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Our ability to compete successfully will significantly depend upon our ability to effectively complete necessary clinical studies and regulatory approval processes, and effectively commercialize approved products. The primary competitive factors that will affect the commercial success of any product candidate for which we have or may receive marketing approval include efficacy, safety and tolerability profile, acceptance by physicians, ease of patient compliance, dosing convenience, price, insurance and other reimbursement coverage, patent position, distribution, and marketing. Our competitors may obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial, technical, and human resources to deploy than we do towards the discovery and development of product candidates, as well as obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our existing and potential future competitors also have significantly more experience in manufacturing and commercializing drugs that have been approved for marketing. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration agreements with larger more established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales force, and management personnel and establishing clinical study sites and patient enrollment and retention for clinical studies. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for prostate cancer, uterine fibroids or endometriosis by a competitor could render our product candidates non-competitive or obsolete or reduce the demand for our product candidates before we can recover our development and commercialization expenses.

Although ORGOVYX is the first and only oral GnRH receptor antagonist for adult patients with advanced prostate cancer approved by the FDA in the U.S., we may face competition from various drugs approved for the treatment of prostate cancer, such as Lupron Depot® (AbbVie Inc.), Eligard® (Tolmar Pharmaceuticals), Firmagon® (Ferring Pharmaceuticals), and Camcevi™ (Accord BioPharma (U.S.)). LHRH agonists, such as leuprolide acetate, are the current standard of care treatment used to lower testosterone in men with advanced prostate cancer. These have been approved for three decades and are administered by injection on a monthly, quarterly, every four months or every six months basis and are the most direct competitor for ORGOVYX. Degarelix, a depot GnRH antagonist requiring monthly injections, is approved for use to lower testosterone in men with advanced prostate cancer, but clinical use is limited likely due to the requirement for monthly high-volume injections with a rate of injection site reactions of approximately 35%. Other oral medications used for androgen deprivation therapy include androgen receptor inhibitors such as enzalutamide, apalutamide and darolutamide, androgen biosynthesis inhibitors such as abiraterone acetate, and antiandrogens such as bicalutamide and flutamide, each commonly used in combination with a GnRH receptor antagonist or LHRH agonist.

MYFEMBREE is the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women approved by the FDA in the U.S., with a treatment duration of up to 24 months. MYFEMBREE competes with ORIAHNN®, an oral GnRH receptor antagonist combination therapy (one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening), which was approved by the FDA and launched by AbbVie in June 2020 for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. In addition, ObsEva SA's NDA for linzagolix, an oral GnRH receptor antagonist for the treatment of uterine fibroids for use with and without add-back therapy, was accepted for review by the FDA in November 2021 and the FDA set a target action date of September 13, 2022.

We consider MYFEMBREE's (if approved) most direct competitor for the treatment of pain associated with endometriosis to be ORILISSA™ (elagolix), an oral GnRH receptor antagonist, which was approved as monotherapy (150 mg once a day or 200

mg twice a day) by the FDA and launched by AbbVie in August 2018 for the management of moderate-to-severe pain associated with endometriosis. AbbVie also has one ongoing Phase 3b study of elagolix in combination with hormonal therapy in women with pain associated with endometriosis. In April 2021, AbbVie posted the results of a Phase 3 study evaluating elagolix 200 mg twice a day with and without hormonal add-back therapy in women with moderate to severe endometriosis associated pain, showing that the study met its primary endpoint. In May 2019, ObsEva initiated a Phase 3 program evaluating linzagolix in women with endometriosis-associated pain, evaluating a lower 75 mg monotherapy dose and a higher 200 mg dose with hormones; however, one of the Phase 3 studies being conducted in the U.S. was terminated due to enrollment challenges. ObsEva reported in January 2022 positive Phase 3 study results for the higher dose with hormones, but the lower 75 mg monotherapy dose did not meet one of the co-primary objectives of nonmenstrual pelvic pain.

We believe the development of multiple GnRH receptor antagonists by other biopharmaceutical companies adds further validation to the therapeutic relevance of GnRH as a target for the treatment of women's health and endocrine diseases and will help fuel growth in this market which has lacked innovative new medical therapies.

In addition to other GnRH receptor antagonists and selective progesterone receptor modulators in active development, we are aware of other biotechnology and pharmaceutical companies as well as academic institutions, government agencies, and private and public research institutions that are developing, and may in the future develop and commercialize, products for gender-specific hormone disorders.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries for relugolix, MVT-602 and any future products and product candidates. We seek to protect our proprietary position by, among other methods, filing and in-licensing U.S. and foreign patents and patent applications. We also rely on trademarks, trade secrets and know-how to develop and maintain our proprietary position.

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent terms can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office ("USPTO") in examining the patent application (patent term adjustment ("PTA")) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension ("PTE")), or both. We cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our products or product candidates. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products.

Under the Takeda License Agreement, we are the exclusive licensee of multiple granted U.S. patents, and pending patent applications, as well as patents and patent applications in numerous foreign jurisdictions relating to relugolix and MVT-602.

For relugolix, we are the exclusive worldwide licensee, excluding the Takeda Territory. These patents and patent applications cover the relugolix molecule and certain analogs and solid forms; the use of relugolix to treat prostate cancer, hysteromyoma (uterine fibroids), and endometriosis; methods of manufacturing and certain intermediates; and certain formulations. The patent family directed to the relugolix molecule will expire in 2024, subject to any extension of patent term that may be available in a particular country. We have applied for PTE based on the approval of ORGOVYX for a patent covering relugolix. If granted, the term of the extended patent may be extended for up to five years, or 2029. Based on the approval of RYEQO in Europe for the treatment of uterine fibroids, we have also filed Supplementary Protection Certificate ("SPC") applications based on the European patent directed to the relugolix molecule. If issued, the SPCs should expire in 2029 in individual European countries in which filed. The patents and patent applications, if issued, directed to methods of manufacturing relugolix and relevant intermediates will expire in 2033, subject to any adjustment or extension of patent term that may be available in a particular country. The patents and patent applications, if issued, directed to formulations of relugolix will expire in 2036, subject to any adjustment or extension of patent term that may be available in a particular country. We have filed patent applications directed to uses of relugolix combination therapy in treating, among other conditions, heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis. The granted U.S. patent and pending patent applications in this patent family are co-owned with Takeda under the Takeda License Agreement. This patent and these applications, if issued, will expire in 2037 not including any adjustments or extensions. We have also filed patent applications directed to the use of relugolix as a monotherapy to treat advanced prostate cancer. The granted U.S. patents, and patent applications in this patent family, if issued, will expire in 2037, not including any adjustments or extensions. These patents and patent applications are also co-owned with Takeda. We have also filed patent applications directed to particular crystalline forms of relugolix and certain relugolix solvates. The patent applications in these families, if issued, will expire in 2040, not including any adjustments or extensions. The relugolix crystalline form application is co-owned with Takeda under the Takeda License Agreement, and the relugolix solvates application is owned by Myovant Sciences GmbH. We have also filed a patent application directed to uses of relugolix combination therapy to treat prostate cancer, uterine fibroids, or endometriosis. The patent applications resulting from this

family, if issued, will expire in 2041, not including any adjustments or extensions. This application is owned by Myovant Sciences GmbH. We have also filed patent applications directed to fixed dose combination formulations which, if issued, will expire in 2041, not including any adjustments or extensions. These applications are owned by Myovant Sciences GmbH.

For MVT-602, we are the exclusive worldwide licensee of multiple patents and patent applications in the U.S. and numerous foreign jurisdictions. These patents and patent applications cover the MVT-602 oligopeptide and its use in treating advanced prostate cancer, as well as certain sustained release formulations containing MVT-602. The patent family directed to the MVT-602 molecule and method of use expires in 2028 in the U.S. (because of PTA) and in 2026 ex-U.S., subject to any adjustment or extension of patent term that may be available in a particular country. The patents directed to sustained-release formulations of MVT-602, if issued, would expire between 2030 and 2031, subject to any adjustment or extension of patent term that may be available in a particular country. We intend to apply for PTE for a patent covering MVT-602. If granted, the patent term covering MVT-602 may be extended. We are also the owner of patents and patent applications directed to uses of MVT-602 in treating infertility. The patents and applications, if issued, in this family will expire in 2037 subject to any adjustment or extension of patent term that may be available in a particular country. We have licensed additional patents and patent applications from Takeda directed to other oligopeptides that target the same pathway as MVT-602.

In addition to patents, we also rely upon trademarks, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We maintain both registered and common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Obtaining patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents which could be used to prevent or attempt to prevent us from commercializing our product candidates. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

Orange Book Listing

An NDA sponsor must identify to the FDA patents that claim the drug substance or drug product or approved method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. Any applicant who files an ANDA or a 505(b)(2) NDA must certify, for each patent listed in the Orange Book for the Referenced Listed Drug ("RLD") that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, (2) such patent has expired, (3) the listed patent will expire on a particular date and approval is sought after patent expiration, or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. An ANDA or 505(b)(2) applicant may also submit a statement that it intends to carve-out from the labeling of its product an RLD's use that is protected by exclusivity or a method of use patent. The fourth certification described above is known as a Paragraph IV certification. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the reference NDA holder. The reference NDA holder and patent owners may initiate a patent infringement lawsuit in response to the Paragraph IV notice. We intend to defend vigorously any patents for our approved products. Six patents and four patents are currently listed in the Orange Book for ORGOVYX and MYFEMBREE, respectively.

Government Regulation

United States- FDA Drug Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and other regulations requires the expenditure of substantial time and financial resources. The Federal Food, Drug, and Cosmetic Act ("FDCA"), and other federal and state statutes and regulations, govern, among other things, the research, development, nonclinical and clinical testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines,

refusals of government contracts, restitution, disgorgement of profits, or civil penalties or criminal investigations and penalties brought by the FDA, the Department of Justice or other governmental organizations.

No drug product candidates may be marketed in the U.S. until the drug has received FDA approval. The steps required before a drug may be approved for marketing in the U.S. generally includes the following:

- completion of extensive nonclinical laboratory tests, animal studies, and formulation studies conducted in accordance with the FDA's Good Laboratory Practices ("GLP");
- submission to the FDA of an Investigational New Drug application ("IND") for human clinical testing, which must become effective before human clinical studies may begin in the U.S.;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with Good Clinical Practices ("GCP") to establish the safety and efficacy of the drug for each proposed indication;
- the preparation and submission of an NDA or sNDA to the FDA for commercial marketing;
- FDA acceptance, review, and approval of the NDA or sNDA, which might include an advisory committee; and
- satisfactory completion of any FDA pre-approval inspections of a manufacturing facility or facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced and tested to assess compliance with cGMP and of selected clinical investigators or contract research organizations for their compliance with GCP.

Regulatory authorities or an IRB or the study sponsor may suspend a clinical study at any time on various grounds including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Nonclinical studies include laboratory evaluations of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product candidate. The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical study protocol. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical study as outlined in the IND prior to that time. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical study can begin. The FDA may nevertheless initiate a clinical hold after the 30 days if, for example, significant public health issues arise. A separate submission to the existing IND must be made for each successive clinical study conducted during product development. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical studies are typically conducted in three sequential phases, but the phases may overlap. These phases generally include the following:

- Phase 1 - Studies, which involve the initial introduction of the product candidate into humans, are initially conducted in a limited number of subjects to assess pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 1 studies may also be conducted to assess potential for drug interactions or drug exposure in patients with renal or hepatic impairment.
- Phase 2 - Studies are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate the preliminary efficacy, metabolism, pharmacokinetics, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks.
- Phase 3 - Phase 3 studies, also called pivotal or registration studies, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical study sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical studies to demonstrate the efficacy of the drug. A single Phase 3 clinical study with other confirmatory evidence may be sufficient in rare instances where the study is a large multi-center study demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and where confirmation of the result in a second study would be practically or ethically impossible.

The FDA may require, or companies may pursue, additional clinical studies after a product is approved. These Phase 4 studies may be deemed a condition to be satisfied after a drug receives approval. Failure to satisfy such post-marketing commitments can result in FDA enforcement action, up to and including withdrawal of approval.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing, and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional nonclinical, preclinical, or other studies.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. The FDA's goal is to review applications within ten months of the filing date or, if the application relates to an unmet medical need in a serious or life-threatening indication and is granted priority review, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a drug candidate is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or some of the facilities at which the drug is manufactured or tested.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh the potential risks. A REMS can include a medication guide, a communication plan for healthcare professionals, and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry, and other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in formulation, indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or sNDA before the change can be implemented. An sNDA for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing an sNDA as it does in reviewing NDAs.

Post-Approval Requirements

Approved drugs that are manufactured or distributed in the U.S. pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, REMS, or surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to GMP requirements after approval, including for supply chain traceability. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration

with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with GMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with GMP requirements. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in, among other things:

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

Foreign Regulation

In addition to regulations in the U.S., we are subject to laws and regulations of other countries governing clinical studies and the manufacturing, commercial sales and distribution of our products outside the U.S. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical studies or marketing of the product in foreign countries or economic areas, such as the EU. Although many of the issues discussed above with respect to the U.S. apply similarly in the context of foreign countries and the EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be shorter or longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws and Compliance Requirements

Our current and future business operations are subject to additional healthcare laws, regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws.

Because we commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we have a Code of Business Conduct and Ethics and other corporate compliance policies, but 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. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, 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, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Anti-Kickback Laws

U.S. federal laws, including the federal Anti-Kickback Statute, prohibit fraud and abuse involving state and federal healthcare programs, such as Medicare and Medicaid. These federal Anti-Kickback Statutes, among other things, make it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration, directly or indirectly, that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item, or service for which payment may be made under a federal healthcare

program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including cash, gifts or gift certificates, improper discounts, and free or reduced-price items and services. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act ("ACA"), to a stricter intent standard such that a person or entity no longer needs to have actual knowledge of the statute or the specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

Federal and State Prohibitions on False Claims

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Many states have enacted similar laws modeled after the federal civil False Claims Act that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to all payers.

Federal Prohibitions on Healthcare Fraud and False Statements Related to Healthcare Matters

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created new federal civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers. Like the federal Anti-Kickback Statute, the ACA broadened the reach of certain criminal healthcare fraud statutes under HIPAA by amending the intent requirement such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

Healthcare Privacy and Security Laws

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, impose specific requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individual identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information. In addition, certain state and foreign laws, regulations, standards and regulatory guidance govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We have conducted, and may continue to conduct, clinical studies or continue to enroll subjects in our ongoing or future clinical studies in certain jurisdictions in which we may be subject to additional privacy restrictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to the greater of 20 million Euros or 4% of annual global revenue. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Data protection authorities from the different EU member states have issued limited guidance, may interpret the GDPR and national laws differently and may impose additional requirements, which complicates the effort to comply with these laws. Further, Brexit has created uncertainty with regard to data protection regulation in the U.K. In particular, it is unclear whether, post-Brexit, the U.K. will enact data protection legislation equivalent to the GDPR and how data transfers to and from the U.K. will be regulated.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Some states require the posting of information relating to clinical studies. Additionally, California enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of California consumers and households. The CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and requires deletion of their personal information, opting out of certain personal information sharing, and receiving detailed information about how their personal information is collected, used and shared. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical studies data, as well as HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs, and adversely affect our business.

Physician Payments Sunshine Act

There has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA through the enactment of the Physician Payments Sunshine Act, imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members.

Many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs. We may also be subject to 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, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, as well as state and local laws that require the registration of pharmaceutical sales representatives. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

Foreign Corrupt Practices Act

We are subject to the Foreign Corrupt Practices Act of 1977, as amended, ("FCPA"), which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or otherwise influence a person working in an official capacity to obtain a business advantage. The FCPA also requires public companies whose securities are listed in the U.S. to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of suppliers, vendor or other third-party relationships, termination of necessary licenses or permits, and legal or equitable sanctions. Other internal or governmental investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Healthcare Reform

Public policy, laws, regulations, and guidelines for the pharmaceutical industry can be made across the executive and legislative branches of government and at the federal, state and local level. Efforts to expand access, enhance quality and contain costs are fundamental underpinnings of most healthcare reform measures. While well intended, some policies could have an adverse effect, such as cost containment programs to limit the growth of health care costs, including price controls, restrictions on reimbursement, and other fundamental changes to the healthcare delivery system.

At any time, legislation can be drafted, introduced, and passed in the U.S. Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, coverage, and reimbursement of products regulated by the FDA or other government agencies. For example, in 2022 Congress is expected to pass the Prescription Drug User Fee Act Reauthorization for years 2023 to 2028, as well as annual funding for the FDA and U.S. Department of Health and Human Services ("HHS"); and may consider other major legislation such as the "Build Back Better Act" aimed in part at lowering drug prices and reforming Medicare. Previously passed legislation that materially impacts prescription drug manufacturers will also become effective in the near-term. For example a provision included in the American Rescue Plan Act of 2021 will eliminate the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, effective beginning January 1, 2024. Further, Congress is considering additional healthcare reform measures. It is also possible that additional government action is taken in response to the COVID-19 pandemic.

Federal agencies including the HHS and its Centers for Medicare and Medicaid Services ("CMS") may also issue rules and guidance that impact coverage, reimbursement, and pricing policy for prescription drugs. For example, CMS previously finalized a regulation removing safe harbor protection for price reductions from drug manufacturers to plan sponsors under Medicare Part D, either directly or indirectly through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2026. Further, in response to the Biden administration's July 2020 executive order aimed at prescription drugs, HHS released a Comprehensive Plan for Addressing High Drug Prices which provides principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles.

Finally, U.S states also have partial jurisdiction over coverage of prescription drugs by commercial health insurance plans and Medicaid. Over the course of the state legislative sessions, we are closely tracking legislation that affects drug pricing and access in these channels. This includes legislation attempting to cap drug prices, expand 340B pricing, and require drug manufacturer rebates to be passed through to patients at the point-of-sale; as well as efforts to reduce or eliminate prior authorization and step therapy, and to protect manufacturer-provided financial assistance for patients.

Coverage, Reimbursement and Pricing

Sales of any products for which we have obtained or, in the future, may obtain regulatory approval, depend, in part, on the coverage and reimbursement status of those products. In the U.S., sales of any products for which we have received or, in the future, may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payers. Third-party payers include government programs including Medicare Part D, Medicaid, TRICARE and the Veterans Administration, as well as private payers including pharmacy benefit managers, health plans, self-insured organizations, and other plan administrators. Other countries and jurisdictions will also have their own unique mechanisms for approval and reimbursement.

The process for determining whether a payer will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list or formulary which might not include all of the FDA-approved products for a particular indication. Third-party payers may also refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Further, private payers often follow the coverage and payment policies established by certain government programs, such as Medicare and Medicaid, which require manufacturers to comply with certain rebate, price reporting, and other obligations. For example, the Medicaid Drug Rebate Program, which is part of the Medicaid program (a program for financially needy patients, among others), requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services under which the manufacturer agrees to report certain prices to the government and pay rebates to state Medicaid programs on outpatient drugs furnished to Medicaid patients, as a condition for receiving federal reimbursement for the manufacturer's outpatient drugs furnished to Medicaid patients. Further, in order for a pharmaceutical product to receive federal reimbursement under Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the Public Health Service's 340B drug pricing program.

Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payers to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our approved products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any approved products will therefore depend substantially on the extent to which costs of the product will be paid by third-party payers. Additionally, the market for any approved products depends significantly on access to third-party payers' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payers provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payer to payer. One third-party payer's decision to cover a particular medical product or service does not ensure that other payers will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will likely be a time-consuming process.

Third-party payers are increasingly challenging the prices charged for medical products and services, and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products, among other controls. Adoption of price controls or other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payers do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our approved products or a decision by a third-party payer to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our approved products or additional pricing pressures.

The degree of market acceptance of ORGOVYX will also depend on the acceptance and degree of adoption by institutional treatment pathways and institutional, local, and national clinical guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, or the NCCN Guidelines, the American Urological Association ("AUA") guidelines, American Society of Clinical Oncology ("ASCO") Clinical Practice Guidelines, or other country-specific guidelines. This could also be the case for MYFEMBREE in terms of inclusion in practice guidelines such as those from the American College of Gynecology ("ACOG"), American Society for Reproductive Medicine ("ASRM"), American Association of Gynecologic Laparoscopists ("AAGL"), or other country-specific guidelines. In the U.S., healthcare providers may refer to these guidelines related to patient treatment decisions. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Brexit and the Regulatory Framework in the United Kingdom

In December 2020, the U.K. and the EU agreed on a trade and cooperation agreement, under which the U.K. and the EU will now form two separate markets governed by two distinct regulatory and legal regimes. The trade and cooperation agreement covers the general objectives and framework of the relationship between the U.K. and the EU, including as it relates to trade, transport and visas. Under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire EU single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the EU. Depending on the application of the terms of the trade and cooperation agreement, we and others could face new regulatory costs and challenges.

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, the U.K. is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the U.K. Until January 2023, it is possible for the MHRA to rely on a decision taken by the EC on the approval of a new marketing authorization via the centralized procedure. However, it is unclear whether the MHRA in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive after

such time. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us and our collaboration partners from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

The U.K.'s vote to exit the EU could also result in similar referendums or votes in other European countries in which we and our collaboration partners conduct business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the U.K. from the EU will have and how such withdrawal may affect us.

Other Applicable Laws

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of the New York Stock Exchange, on which our common shares are traded.

We are also subject to various other federal, state, and local laws and regulations, including those related to safe working conditions, and the storage, transportation, or discharge of items that may be considered hazardous substances, hazardous waste, or environmental contaminants.

Our operations extend to countries around the world, and many of these jurisdictions have established privacy legal frameworks with which we, our customers, our collaboration partners, or our vendors must comply.

Environment, Social, Governance, and Human Capital

Governance and Leadership

Our commitment to integrating sustainability across our organization begins with our board of directors, which has oversight of strategy and risk management related to Environmental, Social and Governance ("ESG").

Business Ethics

We are committed to creating an environment where we are able to excel in our business while maintaining the highest standards of business conduct and ethics. Our Code of Business Conduct and Ethics ("Code of Conduct") reflects the business practices and principles of behavior that supports this commitment, including our policies on bribery, corruption, conflicts of interest, insider trading, and our whistleblower program. We expect all of our directors, officers, and employees to read, understand, and comply with the Code of Conduct and its application to the performance of his or her business responsibilities.

Environmental Commitment

We are committed to protecting the environment and attempt to mitigate any negative impact of our operations, promoting reuse and recycling and conserving resources, where feasible. We have safety protocols in place for handling biohazardous waste in our operations, including in our clinical trials, and we use third-party vendors for biohazardous waste and chemical disposal.

Social Responsibility

We believe a transformative effort is needed to make significant progress for greater access to medicines, continued scientific discovery and innovation, and removing barriers to access and quality of care for the patients we serve. We work to elevate the conversation around women's health and bring much-needed attention to conditions such as uterine fibroids and endometriosis. In October 2019, we announced Female Forward Together, a cross-sector coalition committed to advancing research, education, and action for women's health. This coalition brings together expertise in healthcare, digital health, and advocacy to elevate women's health.

We believe that significant challenges remain for men with prostate cancer despite recent progress. Prostate cancer is the second most common cancer in men and the second leading cause of cancer death in the U.S. We believe prostate cancer also has the largest racial disparity of any major cancer, killing Black men twice as often as White men. Despite new medications and increased public awareness, there remains an inadequate focus on the full spectrum of the mental and physical health of men with prostate cancer. We are working across sectors to address the complex set of challenges that these men face, including persistent racial disparities. In June 2020, we announced Forward Momentum, a cross-sector coalition working on innovative projects to increase diversity in research and develop new digital resources for men with prostate cancer. This coalition brings together expertise in healthcare, research, and advocacy to address the stigma, education, and other barriers for men with prostate cancer.

Our goal is to maximize access to our approved medicines. Our access within federally funded programs such as Medicare, Medicaid, and VA/TRICARE is comprehensive. We have also established various support programs for patients, including co-pay support for commercially-insured patients, free trial programs, and patient assistance for uninsured and under-insured patients.

Human Capital

As of March 31, 2022, we had 579 full-time employees, all of whom are expected to be guided by our vision and values and by an underlying set of ethical principles. We are committed to treating each of our employees fairly, and to maintaining employment practices based on equal opportunity for all employees. We respect each other's privacy and treat each other with dignity and respect irrespective of age, race, color, sexual preferences, nationality, or physical condition. We are committed to providing safe and healthy working conditions and an atmosphere of open communication for all our employees.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We emphasize a number of measures and objectives in managing our human capital assets, including employee engagement, development and training, talent acquisition and retention, employee wellness, diversity, inclusion, and compensation and pay equity. We provide our employees with competitive salaries, bonuses, opportunities for equity ownership, development opportunities that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. In addition, we collect employee feedback to ensure two-way communication, measure employee engagement and identify opportunities for improvement.

We believe that developing a diverse and inclusive culture is critical to continuing to attract and retain the top talent necessary to deliver on our business strategy. As such, we are investing in a work environment where our employees feel inspired and included. We continue to focus on extending our diversity and inclusion initiatives across our entire workforce. In addition, we work to ensure our employees understand and embrace our commitment to our patient community and core values.

Response to COVID-19

Beginning in March 2020, we have supported our employees and government efforts to curb the COVID-19 pandemic through a multifaceted communication, infrastructure, and behavior modification and enforcement effort. These actions have included:

- establishing a COVID-19 task force, which provides clear and regular COVID-19 policies, safety protocols, and updates to all employees;
- decreasing density and increasing physical distancing in workplaces for employees working onsite by scheduling adjustments and adding work from home flexibility;
- adjusting attendance policies to encourage those who are sick to stay at home;
- increasing cleaning protocols in our offices;
- providing additional personal protective equipment and cleaning supplies;
- implementing protocols to address actual and suspected COVID-19 cases and potential exposure;
- prohibiting all domestic and international non-essential travel for all employees through mid-2021; and
- complying with all local and national public health advisories.

In December 2021, we adopted a policy to require proof of vaccination as a condition of employment for our U.S.-based employees, subject to medical and religious exemptions, or as otherwise required by law. In April 2022, we reopened our offices, and our employees began to return to work onsite on a voluntary basis with specific safety protocols.

Corporate Information

We are an exempted company limited by shares incorporated under the laws of Bermuda in February 2016 under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, SW1Y 4LB, United Kingdom, and our telephone number is +44 (207) 400 3351. We maintain additional offices in Brisbane, California and Basel, Switzerland. Our common shares are listed on the New York Stock Exchange under the symbol "MYOV."

Available Information

We make our filings with the SEC, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. The SEC maintains an internet site that contains reports, proxy and information statements, and other information. The address of the SEC's website is www.sec.gov.

Our corporate website is www.myovant.com. Investors and other interested parties should note that we also use our media and investor relations website (investors.myovant.com) and our social media channels to publish important information about Myovant that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our investor relations website and social media channels, in addition to our SEC filings.

The content on any website or social media channel referred to in this Annual Report is not included as part of, or incorporated by reference into, this Annual Report. Further, our references to website URLs are intended to be inactive textual references only.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K ("Annual Report"), including the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this Annual Report occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline and you could lose all or part of your investment in our common shares.

Risks Related to Commercialization of Our Drug Products

Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.

We received approval for ORGOVYX (relugolix 120 mg) in December 2020 from the U.S. Food and Drug Administration ("FDA") for the treatment of adult patients with advanced prostate cancer, and received approval for MYFEMBREE (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids. We continue to invest a significant portion of our efforts and financial resources in the commercialization of these drug products in the U.S. The ability for us and/or our collaboration partner, Pfizer Inc. ("Pfizer"), to generate net product revenues from our drug products will depend upon the size of the markets, the number of competitors in such markets and numerous other factors, including:

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which our drug products are approved for sale;
- successfully establishing and maintaining commercial third-party manufacturers and having adequate commercial quantities of our drug products manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of our drug products by physicians, patients and the healthcare community;
- the acceptance of pricing and placement of our drug products on payers' formularies and the associated tiers;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of safety and efficacy of our drug products in comparison to competing products, including through differentiated approved product labeling; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

Further, in July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for

duration of use. Since RYEQO's approvals in the EU and U.K., our collaboration partner, Gedeon Richter Plc. ("Richter") has launched RYEQO in 17 countries. In April 2022, the EC approved ORGOVYX® (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. Our collaboration partner, Accord Healthcare, Ltd. ("Accord"), will be responsible for the commercial launch of ORGOVYX in Europe. The success of Richter in generating net revenue from RYEQO and the success of Accord in generating revenue from ORGOVYX are also subject to many of the factors described above. If we and/or our collaboration partners do not achieve one or more of these factors in a timely manner or at all, we and/or our collaboration partners could experience significant delays or an inability to successfully commercialize any of our drug products, which would materially harm our business.

Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.

Our drug products may fail to gain sufficient market acceptance by physicians, patients, third-party payers, or others in the medical community. If any of our drug products do not achieve an adequate level of acceptance, we may not generate significant net product revenue or become profitable. The degree of market acceptance of our drug products is dependent on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments, including the convenience and ease, or duration of administration;
- the prevalence and severity of any side effects;
- the acceptability of the price of our drug products relative to other treatments;
- the content of the approved product labels and our ability to make compelling product claims;
- the effectiveness and adequacy of our and our collaboration partner's sales and marketing efforts;
- the patients' out-of-pocket costs in relation to alternative treatments;
- the willingness of potential patient population to try new therapies and of healthcare providers to prescribe these therapies;
- the breadth and cost of distribution support;
- the effectiveness of our patient assistance and support programs;
- the availability of third-party payer coverage and adequate reimbursement;
- whether diagnosis and treatment rates change in advanced prostate cancer, heavy menstrual bleeding associated with uterine fibroids, or other indications for which our drug products were approved; and
- any restrictions on the use of our drug products together with other medications.

The degree of market acceptance of ORGOVYX will also depend on the acceptance and degree of adoption by institutional treatment pathways and institutional, local, and national clinical guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, the American Urological Association guidelines, American Society of Clinical Oncology Clinical Practice Guidelines, or other country-specific guidelines. This could also be the case for MYFEMBREE in terms of inclusion in practice guidelines such as those from the American College of Gynecology, American Society for Reproductive Medicine, American Association of Gynecologic Laparoscopists, or other country-specific guidelines. In the U.S., healthcare providers may refer to these guidelines with respect to patient treatment decisions. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products.

If we and our collaboration partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.

To market our drug products successfully, we must continue to develop and maintain our capabilities in sales, market access, marketing, distribution, and other commercial functions, either on our own or with our third-party collaboration partners. We have made arrangements regarding some of these functions in certain markets with third-party collaboration partners. For example, on August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion Pharmaceuticals Inc. ("Sunovion") pursuant to which, among other things, Sunovion has agreed to provide to us certain market

access services with respect to the distribution and sale of ORGOVYX and MYFEMBREE in the U.S. On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which Richter will commercialize relugolix combination tablet for uterine fibroids and endometriosis (if approved) in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. On May 5, 2022, we entered into the Accord License Agreement pursuant to which Accord will commercialize ORGOVYX in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa and India. If Sunovion, Pfizer, Richter, Accord or any other collaboration partners we may engage in the future, fail to perform or satisfy its obligations under their respective agreements with us or terminate their relationship with us, the sales, market access, marketing and/or distribution of our drug products would be delayed or may not occur. In addition to the third-party collaboration arrangements described above, we continue to develop and maintain our own sales, market access, marketing, distribution and other commercial capabilities. There are significant expenses and risks involved with maintaining our own sales, market access, marketing, distribution, and other commercial capabilities, including: (i) our ability to recruit, train, and retain adequate numbers of qualified and effective sales, market access and marketing personnel; (ii) our ability to attain access to adequate numbers of healthcare professionals to prescribe any approved drugs; (iii) our ability to negotiate coverage and reimbursement for our products with payers at reasonable rebate or discount levels; (iv) our ability to negotiate competitive provider contracts to ensure access in in-office dispensing pharmacies; and (v) unforeseen costs and expenses associated with establishing and maintaining our own sales, market access, marketing, distribution, and other commercial capabilities. The COVID-19 pandemic may negatively impact our and our collaboration partners' ability to maintain commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize our drug products.

We and our collaboration partner, Pfizer, launched ORGOVYX in the U.S. in January 2021 and MYFEMBREE in the U.S. in June 2021. Further, our collaboration partner, Richter, recently launched RYEQO in Europe. We and/or our collaboration partners continue to expend significant time and resources to market, sell, seek reimbursement, and distribute these drug products to physicians and the medical community in a credible, persuasive, and compliant manner consistent with applicable laws. There is no guarantee that the strategies, tactics, marketing messages, or the distribution and reimbursement capabilities that we or our collaboration partners have developed will be successful. Specifically, for distribution of these drug products, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If we or our collaboration partners are unable to perform effectively, our ability to realize sales targets and the return on our investment in developing these drug products will suffer.

Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.

Our and Pfizer's ability to commercialize ORGOVYX and MYFEMBREE successfully in the U.S. will depend in part on the extent to which coverage and reimbursement for ORGOVYX and MYFEMBREE will be available from third-party payers, including government health administration authorities (such as the Department of Veterans Affairs, and the Department of Defense and state Medicaid programs), Medicare Part D plan sponsors, and private health insurers, such as pharmacy benefit managers, health plans, and self-insured organizations. In the U.S., no uniform policy for coverage for products exists among third-party payers. Third-party payers decide which drugs they will pay for, what steps prescribers must take to obtain authorization for patients to fill their prescriptions, and how much patients must pay out of their own pocket. Payer decisions regarding the extent of coverage to be provided for any of our product candidates that obtain marketing approval will be made on a plan-by-plan basis. Additionally, a third-party payer's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. Each third-party payer determines whether or not it will provide coverage for a drug, what amount it will reimburse for the drug, on what tier of its formulary the drug will be placed, and whether to require step therapy or prior authorizations. The position of a drug on a formulary generally determines out-of-pocket costs that a patient will pay 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, providers prescribing such therapies and pharmacies that dispense drugs generally rely on third-party payers to reimburse all or part of the associated healthcare and drug costs. Coverage from both governmental healthcare programs, such as Medicare Part D and Medicaid, and coverage by private commercial payers are critical to ORGOVYX's and MYFEMBREE's commercial success. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Providers may also participate in shared savings programs with government or commercial payers that may also create barriers to use for innovative drugs. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system that may impact drug coverage, reimbursement for drugs, and patient out-of-pocket costs in the U.S. that could affect our ability to successfully commercialize ORGOVYX and MYFEMBREE. These legislative and regulatory changes may negatively impact the coverage, reimbursement, and patient out-of-pocket costs for ORGOVYX, MYFEMBREE and any future drugs, if approved.

We face substantial competition in the commercialization of our approved drug products and our operating results will suffer if we fail to compete effectively.

The commercialization of new pharmaceutical products is highly competitive, and we face substantial competition with respect to our approved drug products. For example, although ORGOVYX is the first and only oral GnRH receptor antagonist for adult patients with advanced prostate cancer approved by the FDA in the U.S., we may face competition from various drugs approved for the treatment of prostate cancer, such as Lupron Depot® (AbbVie Inc.), Eligard® (Tolmar Pharmaceuticals), Firmagon® (Ferring Pharmaceuticals), and Camcevi™ (Accord BioPharma (U.S.)). MYFEMBREE is the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women approved by the FDA in the U.S., with a treatment duration of up to 24 months. MYFEMBREE competes with ORIAHNN®, an oral GnRH receptor antagonist combination therapy (one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening), which was approved by the FDA and launched by AbbVie in June 2020 for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. In addition, ObsEva's NDA for linzagolix, an oral GnRH receptor antagonist, for the treatment of uterine fibroids for use with and without add-back therapy, was accepted for review by the FDA in November 2021 and that the FDA set a target action date of September 13, 2022. We consider MYFEMBREE's (if approved) most direct competitor for the treatment of pain associated with endometriosis to be ORILISSA™ (elagolix), an oral GnRH receptor antagonist, which was approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018 for the management of moderate-to-severe pain associated with endometriosis.

Many of our current and potential future competitors may have significantly more resources that they can deploy to commercialize drugs and may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than our drug products or any product candidate that we may obtain approval or develop. Our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA or other regulatory authority approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations. The availability and pricing of our competitors' products could limit the demand, lead to competitors having preferential payer coverage and limit the price we are able to charge for our drug products or any product candidate that we may obtain approval for or develop. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors.

The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition, and prospects.

If manufacturers obtain approval for generic versions of ORGOVYX, MYFEMBREE, or of products with which they compete, our business may suffer.

Under the U.S. Food, Drug and Cosmetic Act ("FDCA"), the FDA can approve an Abbreviated New Drug Application ("ANDA"), for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product.

The FDCA requires that an applicant seeking approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to ORGOVYX, MYFEMBREE, or products with which they compete, our business would be materially harmed.

If patient safety issues were to arise for any of our drug products, our future sales of our drug products may be reduced, adversely affecting our results of operations.

The data supporting the marketing approvals in the U.S. for ORGOVYX and MYFEMBREE and forming the basis for our product labels for ORGOVYX and MYFEMBREE were obtained in controlled clinical studies of limited duration. As ORGOVYX and MYFEMBREE are used over longer periods of time by patients, including those taking other medicines, we may continue to identify new issues such as safety concerns, drug resistance or interactions of these drug products, which may require us to provide additional warnings or contraindications on our product labels or narrow the approved indications, each of which could reduce the market acceptance of our drug products.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information directly available to the public through websites and other means, e.g., periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action which may potentially negatively impact sales of our drug products. Further, if serious safety, drug resistance or interaction issues arise with any of our drug products, sales could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected. In addition, problems with other drugs marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as any of our drug products could adversely affect commercialization of our drug products.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by our insurance. If we cannot successfully defend ourselves against claims that our drug products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug products;
- the inability to commercialize our drug products;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of clinical studies of our product candidates;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of net product revenue.

Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our common share price to decline.

If we or our collaboration partners are found to have improperly promoted unapproved uses of our drug products, we may be subject to restrictions on the sale or marketing of our drug products and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies, including regulatory authorities outside the U.S., strictly regulate the marketing and promotional claims that are made about drug products, such as ORGOVYX and MYFEMBREE. In particular, promotion for a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, in the case of ORGOVYX and MYFEMBREE, physicians may prescribe ORGOVYX or MYFEMBREE for indications or uses that are inconsistent with the approved label while we and our collaboration partner, Pfizer, may not market or promote such off-label uses. If we or our collaboration partners are found to have promoted such unapproved uses, we may, among other consequences, receive untitled or warning letters and become subject to significant liability, which would materially harm our business. Furthermore, the use of our products for indications other than those approved by the FDA or regulatory authorities outside the U.S. may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm

our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

Physicians' prescribing our products for unapproved uses may also subject us to product liability claims, to the extent such uses lead to adverse events, side effects, or injuries. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Any of these events could harm our business and results of operations and cause our common share price to decline.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the Centers for Medicare and Medicaid Services ("CMS") and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional enforcement and administrative bodies have increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price ("AMP"), and best price ("BP"), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time-consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

Our drug products are complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of our drug products.

Our drug products are complex to manufacture. Notwithstanding the fact that our third-party manufacturers have validated our processes, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. If any such issues were to arise with respect to our drug products or any future products, our business, financial results, or common share price could be adversely affected. Also, see the Risk Factor titled, "We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products."

Risks Related to Commercialization of our Drug Products Outside the U.S. and for our Product Candidates

Our success relies on the successful commercialization of drug products outside the U.S. and the development or commercialization of our product candidates. If we are successful in obtaining regulatory approval for drug products in jurisdictions outside the U.S. or for our product candidates, we will be subject to the same or similar commercialization risks as described above for our approved drug products.

We expect to seek other regulatory approvals for our drug products in jurisdictions outside the U.S. and for our product candidates in the U.S. If we receive regulatory approval for any drug products in jurisdictions outside the U.S. or for our product candidates in the U.S., we will be subject to the same or similar risks we currently face with the commercialization of ORGOVYX and MYFEMBREE, as described under "Risks Related to Commercialization of Our Drug Products" above. For example, in July 2021, the EC, and August 2021, the MHRA, approved RYEQO as the first and only long-term, once-daily oral treatment in the EU and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of

reproductive age, with no limitation for duration of use. Our commercialization partner, Richter, has launched RYEQO in 17 countries since these regulatory approvals. Sufficient coverage and reimbursement are important for Richter to successfully commercialize RYEQO in Europe, but healthcare reimbursement models and reimbursement requirements vary from country to country in Europe. Although RYEQO has been approved in the EU, many countries have not decided on pricing and reimbursement models. Some European countries may choose not to reimburse RYEQO at all or only reimburse RYEQO at a comparatively low price. The commercialization opportunities of RYEQO in Europe may be limited if RYEQO fails to obtain sufficient coverage or reimbursement in certain countries.

Risks Related to Our Financial Position and Capital Requirements

If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.

In the U.S., we began to commercialize ORGOVYX for the treatment of adult patients with advanced prostate cancer in January 2021 and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in June 2021. We also seek to advance additional product candidates through research and clinical development to regulatory approval and commercialization. These activities will require substantial financial resources.

As of March 31, 2022, we had cash, cash equivalents and marketable securities of $434.2 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Annual Report. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase and our future capital requirements are expected to be significant. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of our drug products and for any product candidates that may receive marketing approval in the future;
- the achievement of regulatory milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration agreements;
- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for our drug products and for any product candidates that may receive marketing approval;
- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, RYEQO, and any product candidates;
- the initiation, progress, timing, costs and results of our planned and ongoing clinical studies for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;
- the cost to maintain, expand, and protect our patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the cost of raw materials and manufacture of our drug products, including packaging;

- the costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts; and
- the costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems.

Under the terms of the Sumitomo Pharma Loan Agreement, we may not raise additional capital without obtaining the consent of Sumitomo Pharma Co. Ltd. ("Sumitomo Pharma"). If we do not have sufficient funds to complete the development of, seek regulatory approvals for our product candidates and commercialize our drug products and, if approved, our product candidates, we may be required to delay, limit, reduce, or terminate our drug development programs, commercialization efforts, and/or limit or cease our operations if we are unable to obtain additional capital to support our current operating plan. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development and commercialization efforts.

We are required to meet certain terms and conditions to draw down funds under the Sumitomo Pharma Loan Agreement. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Pharma Loan Agreement. Further, we may be obligated to repay the loans prior to their scheduled maturity date under certain circumstances.

On December 27, 2019, we, one of our subsidiaries, and Sumitomo Pharma entered into the Sumitomo Pharma Loan Agreement, pursuant to which Sumitomo Pharma agreed to make revolving loans to us in an aggregate principal amount up to $400.0 million. As of March 31, 2022, approximately $41.3 million of borrowing capacity remained available to us under the Sumitomo Pharma Loan Agreement. We may draw down additional funds under the Sumitomo Pharma Loan Agreement once per calendar quarter, subject to certain terms and conditions, including the consent of our board of directors and no change of control having occurred with respect to us. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the agreement. In addition, if Sumitomo Pharma fails to own at least a majority of the outstanding common shares of Myovant, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to us, and in which case we would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Furthermore, within 30 days of a change of control having occurred with respect to us, we will be obligated to repay the outstanding amount of loans and accrued interest under the Sumitomo Pharma Loan Agreement.

We may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate may fail to gain regulatory approval or fail to become commercially viable. Since inception, we have incurred significant operating losses. We expect to continue to incur significant operating expenses as we continue commercialization of ORGOVYX and MYFEMBREE in the U.S., continue to develop our product candidates, and prepare for potential regulatory approval and commercialization of our drug products in the U.S. and other jurisdictions. The timing and magnitude of our net income (loss) will depend on the commercial success of our drug products, as well as the timing and commercial success of any product launches, as well as other potential business and operational activities. Likewise, any potential future milestone or royalty payments that we are eligible to earn under our collaboration agreements will depend on the regulatory and commercial success of our drug products and product candidates, if approved. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

The terms of the Sumitomo Pharma Loan Agreement place restrictions on our operating and financial flexibility.

Our obligations under the Sumitomo Pharma Loan Agreement are senior unsecured obligations that are guaranteed on a full and unconditional basis by all our subsidiaries.

The Sumitomo Pharma Loan Agreement also includes customary representations and warranties as well as affirmative and negative covenants. The negative covenants include limitations on additional indebtedness, liens, certain corporate changes, certain restricted payments, investment transactions with affiliates, entry into certain restrictive agreements, change in the nature of business, and use of proceeds. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders.

Additionally, the Sumitomo Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties and certain covenants following any applicable cure period, cross acceleration to certain debt, other failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, certain breaches by us under our Investor Rights Agreement with Sumitovant Biopharma Ltd. ("Sumitovant") and Sumitomo Pharma, dated December 27, 2019, and failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Pharma may terminate its obligations to make loans to us and declare the principal amount of all outstanding loans and other obligations under the Sumitomo Pharma Loan Agreement to become immediately due and payable, and Sumitomo Pharma may take such other actions as set forth in the Sumitomo Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Pharma to make loans to us would automatically terminate and the principal amount of all outstanding loans and other obligations due under the Sumitomo Pharma Loan Agreement would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Pharma to maintain the loans under the Sumitomo Pharma Loan Agreement, we would be required to repay the outstanding principal amount of the loans and if a change of control occurs with respect to us, we would be required to repay the outstanding principal amount of the loans within 30 days of such change of control. We may not have enough available funds or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates, which may limit our growth potential.

Part of our strategy involves identifying and acquiring or in-licensing novel product candidates. We may fail to identify and acquire or in-license product candidates, including for reasons discussed in these risk factors and also:

- the process by which we identify and decide to acquire product candidates may not be successful;
- the competition to acquire or in-license promising product candidates is fierce and many of our competitors are large, multinational pharmaceutical, biotechnology and medical device companies with considerably more financial, development and commercialization resources and experience than we have;
- potential product candidates may, upon further study during the acquisition process, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance; and
- potential novel product candidates may prove to be unsuccessful and may not be effective in treating their targeted diseases.

In addition, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management's attention from our primary business. If we are unable to identify and acquire or in-license suitable product candidates, we will be unable to diversify our product risk. We believe that any such failure could have a significant negative impact on our prospects for future growth.

We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products.

We do not own or operate, and we do not expect to own or operate, facilities for drug substance and drug product manufacturing, storage and distribution, or testing and are subject to the risk that our contract manufacturers become subject to negative circumstances. For example, in June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and clinical supply of relugolix pursuant to which Takeda Limited supplied us with, and we obtained from Takeda, all of our requirements for relugolix drug substance and drug product that were used under our development plans. In May 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda pursuant to which Takeda agreed to manufacture and supply us with certain commercial relugolix drug substance quantities. In addition, in April 2019, we entered into a Commercial Manufacturing and Supply Agreement with Excella GmbH & Co. KG ("Excella") pursuant to which Excella agreed to manufacture and supply us with certain commercial relugolix drug substance quantities.

Takeda is no longer developing MVT-602. Additional process development and manufacturing will be required for us to complete further Phase 2 and Phase 3 clinical studies for MVT-602. Any third-party vendor that we retain for MVT-602 process and formulation development and manufacturing will need certain specialized capabilities required for MVT-602.

If we need to replace a third-party manufacturer, or if any of our third-party manufacturers experience adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approvals and/or the COVID-19 pandemic, we could experience a significant delay in the supply of a product candidate, which could result in a considerable delay in completing our clinical studies, product testing, and potential regulatory approval of our product candidates. In addition, the commercial launch of our product candidates could be delayed and there could be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the regulatory authorities pursuant to inspections that may be conducted after we submit our regulatory applications to such regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and other regulations and laws for the manufacture of relugolix drug substance and drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they may not be able to secure or maintain regulatory approvals for their manufacturing facilities and any applications that we submit to the FDA or other regulatory authorities that list those manufacturing facilities may be negatively affected. Our third-party contract manufacturing facilities must also be in an acceptable state of cGMP compliance and not be subject to a cGMP-related regulatory or enforcement action that limits their ability to manufacture drug substance or drug product. If any of the drug substance or drug product supplied by a contract manufacturing partner cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix could be significantly delayed or otherwise adversely affected. The FDA or other regulatory authority may withhold approval of any pending regulatory applications or supplements in which non-complaint manufacturing facilities are listed.

For example, in June 2020, Takeda received a warning letter from the FDA which indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following its routine inspection of aseptic finished pharmaceuticals manufacturing at Takeda's manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi ("Hikari Facility"). Although this matter was resolved in October 2021, this warning letter required us to remove the Hikari Facility as a manufacturing site from our NDA submissions and to rely on the alternate contract manufacturing organization ("CMO") listed in the NDA (i.e. Excella) to a greater extent than we had originally planned. We also face the risk that our CMOs may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If our CMOs fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for any of our approved drug products and any of our product candidates, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation delays, or other reasons, our development plans and commercialization of any of our approved drug products and any of our product candidates could be significantly delayed or otherwise adversely affected.

Our product candidates contain highly potent compounds and therefore require specialized manufacturing facilities. Depending on actual commercial demand, additional third-party manufacturing facilities will have to be established to meet the demand through technology transfer, process validation and regulatory approval before product manufactured at the new facilities can be marketed. Any delay in the technology transfer and process validation could limit adequate supply to meet our commercial demand.

Further, our reliance on third-party manufacturers entails various risks, including:

- delay or inability to manufacture our drug products;
- failure of the drug substance transferred from a CMO to meet our product specifications and quality requirements;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing and quality 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 drug products or product candidates (if approved) 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;
- adverse inspection findings by the FDA or other regulatory authorities at third-party manufacturing facilities and/or failure to remediate such findings;
- cGMP regulatory or enforcement action at our third-party manufacturing facilities that limit their ability to manufacture drug substance or drug product for commercial use;
- 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 manufacture of another company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

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

Our or our affiliates' employees, independent contractors, advisers, third-party manufacturers, principal investigators, consultants, commercial collaboration partners, service providers, and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory or legal standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees, independent contractors, advisers, third-party manufacturers, principal investigators, consultants, commercial collaboration partners, service providers, and other vendors, or those of our affiliates, may engage in fraudulent, illegal activity, or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other regulatory bodies, including: those laws that require the reporting of true, complete, and accurate information to such regulatory bodies; laws that require manufacturing by cGMP standards; federal, state and foreign healthcare fraud and abuse laws and data privacy laws; or laws and regulations 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 regulations intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. See the Risk Factors titled, "Our current and future relationships with investigators, healthcare professionals, consultants, third-party payers, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties," and "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows." These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commissions, 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 studies, creating fraudulent data in our nonclinical or clinical studies or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have a Code of Business Conduct and Ethics and other corporate compliance policies, but 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.

Business interruptions resulting from effects of pandemics or epidemics, such as the COVID-19 pandemic, may materially and adversely affect our business and financial condition.

The COVID-19 pandemic may materially and adversely affect our business and financial condition. For example, due to the COVID-19 pandemic, most of our employees worked remotely during much of 2020 and 2021, and many of our employees continue to do so on a part-time or full-time basis. Although we devised new ways of working and collaborating, including adopting remote working tools to minimize the disruption to our business activities, employees may be less productive and efficient given competing priorities with home-schooling or caring for sick family members, and employee engagement and productivity may decrease from the stress of the COVID-19 pandemic resulting in delays in the progress of our business. In December 2021, we adopted a policy to require proof of vaccination as a condition of employment for all of our U.S.-based employees, subject to medical and religious exemptions, or as otherwise required by law. The safety protocols we implemented may not prevent employees from contracting COVID-19. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to illness from COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. In April 2022, we reopened our offices and our employees began to return to work onsite on a voluntary basis with specific safety protocols. We have a distributed workforce and our employees have become accustomed to working remotely and working with others who are working remotely for the past two years. However, as we reopen our offices, we may face operational or other challenges as we and our partners, customers, suppliers, vendors and other parties with whom we do business continue to adjust to a hybrid model of remote and onsite work. These challenges may result in operational inefficiencies, employee dissatisfaction, and distractions to management related to such transition, any of which could harm our business.

We believe that the COVID-19 pandemic continues to have an impact on our commercialization activities that is consistent with other companies in our industry. As a result of the COVID-19 pandemic, there have been changes in the practice of medical care and medical education. For example, many healthcare providers initially expanded their utilization of telemedicine to conduct patient visits, and in many regions of the U.S., the ability of commercial and medical affairs field teams to call on healthcare providers was restricted or converted to virtual access. We and our collaboration partner, Pfizer, launched ORGOVYX in the U.S. in January 2021 and MYFEMBREE in the U.S. in June 2021, and to date, Richter has launched RYEQO in 17 countries. Our oncology sales and medical affairs field teams resumed in-person interactions with healthcare providers in January 2021 and our women's health sales and medical affairs field teams began in-person interactions with healthcare providers in June 2021. Despite this, some physician's offices and many hospitals continue to have limited on-site access for pharmaceutical representatives in order to reduce exposure risk for their patients or staff. Conducting these interactions virtually could reduce the number of medical professionals we are able to engage with, limit our ability to engage with important staff members and virtual meetings have been shown to be less impactful than in-person meetings. The cancellation, postponement or virtual formats for medical conferences also limit access to physicians and reduce awareness of information shared at conferences (medical and promotional). Reduced access to healthcare providers may impact or require adjustments to our planned commercialization activities, including the manner in which our field teams engage with healthcare providers and facilities and supplementing field activities with additional marketing spend. The COVID-19 pandemic has also resulted in fewer opportunities for our medical affairs team to present scientific data as multiple medical conferences have been canceled, postponed, or moved to virtual formats and for our regional medical advisors to engage potential prescribers in scientific exchange. We and our collaboration partners may launch other approved products or indications in the COVID-19 environment. Travel restrictions may make it more difficult for us and our collaboration partners, such as Sunovion, Pfizer, Richter, and Accord to maximize the effectiveness of third-party market access, marketing, sales, and distribution capabilities.

In addition, we rely on third parties in the U.S. and in various parts of the world to assist in the conduct of our clinical studies and to supply us with sufficient drug supplies. Our ability to ensure continuous clinical drug supply to patients and our ability to ensure continuous patient follow up and data monitoring for our ongoing clinical studies may be adversely impacted. Likewise, while we currently expect that the drug supply we have on hand or expect to procure will be sufficient to support our ongoing clinical studies, our and our collaboration partners' commercial sales for our approved drug products, our supply chain for raw materials, drug substance and drug product is worldwide, and the duration of the COVID-19 pandemic and its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for our approved drug products and for our product candidates that may receive regulatory approval, or for clinical study materials. If disruptions to our supply chain persist for an extended period of time, our clinical study timelines, our financial condition and our results of operations may be negatively impacted. In addition, the COVID-19 pandemic may impact the FDA's review process and timing of potential approval of our product candidates. Regulatory agency pre-approval inspections are now limited, particularly for sites outside the U.S., and it is not clear if virtual inspections will be required and acceptable.

Future developments regarding COVID-19 remain uncertain and the extent to which the COVID-19 pandemic ultimately impacts our business, financial condition or results of operations will depend on numerous factors, including the magnitude and duration of the pandemic, the distribution, acceptance, and effectiveness of COVID-19 vaccines and treatments, the impact of new and potentially more virulent or transmissible variants of the coronavirus (e.g., the Delta and the Omicron variants,

respectively), the duration of governmental measures to mitigate the pandemic and how quickly and to what extent normal economic and operating conditions can resume, all of which remain uncertain and difficult to predict. Additionally, even after normalcy resumes, there will likely be some permanent changes to how healthcare is provided, how healthcare providers engage with our industry and perhaps how conferences are conducted. None of these changes can be anticipated at this point, nor the potential impact on our business. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S., and establishing and maintaining relationships with healthcare providers, payers, government officials, distributors, manufacturers and other third parties globally.

Conducting business internationally involves a number of risks, including:

- the increased complexity, difficulties and costs inherent in staffing and managing international operations and business practices in different jurisdictions;
- multiple conflicting and changing laws and regulations such as tax laws, trade protection measures, export and import restrictions, employment, immigration and labor laws, privacy and cybersecurity laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- possible failure by us or our distributors to obtain and maintain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- complexities associated with managing multiple payer-reimbursement, pricing and insurance regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced or no protection over intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars (such as the conflict between the Russian Federation and Ukraine) and terrorism, economic weakness, inflation, political instability in particular foreign economies and markets, boycotts, curtailment of trade, sanctions, labor disputes, unexpected changes in tariffs, and other business restrictions, outbreak of disease (such as the COVID-19 pandemic), fires, earthquakes, hurricane, tornado, severe storm, power outage, system failure, typhoons or floods;
- failure to comply with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the EU General Data Protection Regulation (the "GDPR") which introduced strict requirements for processing personal data of individuals within the EU;
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Any of these risks, if encountered, could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows. We have no prior experience in certain countries, and many healthcare companies have found the process of marketing their products in foreign countries to be very challenging.

The withdrawal of the U.K. from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the U.K. and the EU was agreed to in December 2020. Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, the U.K is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency (the "EMA"), and a separate marketing authorization will be required to market our product candidates in the U.K. Until January 2023, it is possible for the MHRA to rely on a decision taken by the EC on the approval of a new marketing authorization via the centralized procedure. However, it is unclear whether the MHRA in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive after such time. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us and our collaboration partners from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the U.K. and the EU, there may be additional non-tariff costs to such trade which did not exist before. Further, should the U.K. diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face 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. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Our internal computer systems, and those of our third-party collaborators, consultants or contractors, may fail or suffer cybersecurity breaches and data leakage, which could result in a material disruption of our business and operations or liabilities that adversely affect our financial performance.

Our computer systems, as well as those of our contract research organizations ("CROs"), CMOs, third-party logistics providers, third-party collaboration partners, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures.

We rely on our third-party providers to implement effective security and data recovery measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of the commercialization of our drug products and our drug development programs. For example, the loss of commercialization information, nonclinical or clinical study data from completed, ongoing or planned clinical studies could result in delays in our commercialization, regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data, access or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, suffer reputational damage, and the further development of any current or future product candidate could be delayed.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. This information includes, among other things, our intellectual property and proprietary information, commercialization activities, and non-clinical or clinical data from completed, ongoing, or planned clinical studies, and the personally identifiable information of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third-parties whom we conduct business with, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches, ransomware attacks, social engineering attacks, supply-chain attacks, and other cyber-attacks. Ransomware attacks are becoming increasingly prevalent and severe. These threats may come from a wide variety of actors, including traditional hackers, employees, sophisticated nation-states, and state-sponsored actors.

Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems and infrastructure or the information technology systems and infrastructure of third parties that support our operations. Furthermore, because of the COVID-19 pandemic, we have adopted a remote workforce model, which increases the risk that our information technology systems and data could be compromised as more of our employees work from home, utilizing network connections outside our premises. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. Although to our knowledge, we have not experienced any material incident or disruption to date, we cannot be certain that we, or third-parties whom we conduct business with, will not be the target of cybersecurity incidents. While we have implemented security measures to data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, California enacted the California Consumer Privacy Act ("CCPA"), which became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used.

The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical study data, and Health Insurance Portability and Accountability Act ("HIPAA") protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical studies and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the GDPR, which has strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the U.K. In particular, it is unclear whether, post Brexit, the U.K. will enact data protection legislation equivalent to the GDPR and how data transfers to and from the U.K. will be regulated. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

The failure to successfully expand and maintain our enterprise resource planning ("ERP") system and other information technology systems could adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

During our fiscal year 2019, we implemented a company-wide ERP system pertaining to certain business, operational, and finance processes. We have continued to optimize and expand this ERP system and have implemented and continue to optimize other systems as a part of our ongoing technology and process improvement initiatives. ERP and other information technology system implementations are complex, expensive and time-consuming projects that require transformations of business, operational, and finance processes. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the ERP system and other information technology systems could adversely affect our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the ERP system and other information technology systems do not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected and could cause us to fail to comply with SEC obligations related to our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business following the implementation or optimization of the ERP system or other information technology systems, our business and results of operations could be harmed.

The phase-out of the London Interbank Offered Rate ("LIBOR"), or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our outstanding variable rate indebtedness with Sumitomo Pharma.

On July 27, 2017, the U.K.'s Financial Conduct Authority (the authority that regulates LIBOR) announced that after 2021, it would no longer compel banks to submit the rates required to calculate LIBOR. The administrator for LIBOR and other inter-bank offered rates, ICE Benchmark Administration ("IBA"), confirmed on March 5, 2021 its previously announced dates for LIBOR cessation. On the same date, the U.K. Financial Conduct Authority announced that 1-week and 2-week USD LIBOR will cease publication after December 31, 2021, as will all non-USD LIBOR tenors, and that 3-month, 6-month and 1-year USD LIBOR will cease publication after June 30, 2023. The interest rate under the Sumitomo Pharma Loan Agreement is calculated based on 3-month LIBOR and, when the publication of 3-month LIBOR is discontinued, we will need to agree with Sumitomo Pharma on a new method of calculating the interest rate under the Sumitomo Pharma Loan Agreement. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the 3-month LIBOR replacement benchmark rate at this time.

In addition, the Federal Reserve or other regulating bodies around the world may raise, or may announce intentions to raise, interest rates. These developments, along with global economic uncertainties and market volatility, the impacts of COVID 19, and the conflict between the Russian Federation and Ukraine, could cause interest rates, including LIBOR and any replacement benchmark rate, to be volatile.

The conflict between the Russian Federation and Ukraine and other government policies and actions could negatively affect our clinical trial sites in Ukraine. We and/or our collaboration partners may not be able to launch our commercial products in the Russian Federation, Ukraine or other regions which may negatively affect our or our collaboration partners' financial results. The uncertain nature, magnitude, and duration of hostilities stemming from such conflict may result in changes in the world's macroeconomic conditions which negatively affect our business operations.

The conflict between the Russian Federation and Ukraine may have a material adverse effect on our ability to adequately conduct certain clinical trial procedures and maintain compliance with the trial protocol in Ukraine, due to the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and clinical trial participants, or as a result of government-imposed curfews, warfare, violence or other governmental action or events that restrict movement. Some patients may not be able to comply with clinical trial protocols if the conflict impedes patient movement or interrupts healthcare services. We may not be able to access sites for monitoring in regions affected by economic, political or social disruptions in Ukraine and we may not be able to obtain data from affected sites going forward. Our collaboration partners could experience disruptions in their supply chains in regions affected by such rising conflict that may have a negative impact on us. If our access to our clinical trial sites and data were to experience significant disruption due to these risks or for other reasons, it could have an adverse effect on the timing of our clinical trials. The ability of the FDA to conduct pre-approval inspections in Ukraine or other disrupted areas could also be adversely affected. In addition, the U.S., the E.U., and the U.K. have adopted comprehensive sanctions, which restrict a wide range of trade and financial dealings with the Russian Federation and Russian persons, as well as certain regions in Ukraine, including by imposing stricter export controls, prohibiting dealings with major Russian banks and credit institutions, and prohibiting trade with the Donetsk and Luhansk regions of Ukraine. These sanctions could also extend to

Russian allies, such as Belarus. We, or our collaboration partners, may not be able to launch our commercial products in Russia, Ukraine or certain regions that are subject to such trade sanctions which may negatively affect our or our collaboration partners' financial projections.

The uncertain nature, magnitude, and duration of hostilities stemming from the conflict between the Russian Federation and Ukraine and potential further sanctions against the Russian Federation, embargoes, regional instability, geopolitical shifts could have a material negative impact on the world's macroeconomic conditions which may result in potential shipping delays, increased market volatility and uncertainty, and increased cost or unavailability of raw materials and fuel, supplies, freight and labor, inflation, and fluctuations in currency exchange rates. These macroeconomic factors could adversely affect our business, supply chain, clinical studies, suppliers or customers. It is not possible for us to predict the broader consequences of this conflict right now and we continue to monitor this situation and the pact to our business.

Risks Related to Clinical Development and Regulatory Approval

Clinical studies are very expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.

Any product candidate will require extensive clinical testing resulting in sufficiently positive outcomes before we are prepared to submit an NDA or other similar application for regulatory approval. Human clinical studies are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The FDA or other regulatory authorities may not agree with our proposed plans for any clinical studies of our product candidates, or any other potential future product candidates, which may delay or prevent the approval of an NDA or similar application. For example, on May 18, 2021, the FDA informed us by teleconference that it placed a partial clinical hold on our Phase 3 SERENE study (MVT-601-050) evaluating relugolix combination tablet for the prevention of pregnancy pending amendment of the study protocol. In August 2021, the FDA informed us that the partial clinical hold on such study was lifted following study protocol amendments. The clinical study process is also very time consuming. The commencement and completion of clinical studies may be delayed or prevented by several factors, including:

- failure to obtain regulatory approval to commence a study or regulatory actions requiring a hold on any of our clinical studies;
- unforeseen safety issues;
- lack of effectiveness during clinical studies;
- identification of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and/or clinical study sites, the terms of which can be subject to extensive negotiations and may vary significantly among different CROs and clinical study sites;
- our determination that the cost of completing the clinical trial and obtaining regulatory approval does not warrant the expense and investment of time by management and our other personnel;
- slower than expected rates of patient recruitment and enrollment or failure to recruit suitable patients to participate in a study;
- failure to open a sufficient number of clinical study sites;
- unanticipated impact from changes in or modifications to clinical study design;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols; for example, missed assessments or impeded access to study sites due to the COVID-19 pandemic or the conflict between the Russian Federation and Ukraine;
- premature discontinuation of study participants from clinical studies or missing data;
- failure to manufacture or release sufficient quantities of relugolix, MVT-602, estradiol, progestin or placebo or failure to obtain sufficient quantities of concomitant medication, that in each case meet our quality standards, for use in clinical studies;
- inability to monitor patients adequately during or after treatment; or

- inappropriate unblinding of study patients or study results.

Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We, the FDA or an institutional review board or other regulatory authority may suspend our clinical studies at any time if it appears that we or our collaborators are failing to conduct a clinical study in accordance with regulatory requirements, including, the FDA's current Good Clinical Practices ("cGCP") or cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our Investigational New Drug application or other submissions or the manner in which the clinical studies are conducted. In addition, product candidates in later stages of clinical development may fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and clinical testing. Results from clinical studies may require further evaluation, delaying the next stage of clinical development or submission of an NDA or other similar application for regulatory approval. Further, we may determine to terminate a clinical trial if we determine that the cost and time of management and our other personnel does not warrant further investment in the clinical trial. Therefore, we cannot predict with any certainty the timing for commencement or completion of current or future clinical studies. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of any product candidates could be harmed, and our ability to generate net product revenue from any product candidates may be delayed. In addition, any delays in our clinical studies could increase our costs, cause a decline in our common share price, slow down the regulatory approval process, and jeopardize our ability to commence product sales and generate net product 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 delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Moreover, principal investigators for our clinical studies 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 authority may therefore question the integrity of the data generated at the applicable clinical study site and the utility of the clinical study itself may be jeopardized. Clinical study sites, CROs, and manufacturing sites may be inspected for compliance with cGCP or cGMP. Any questions about data integrity or significant quality issues could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

We are dependent on the research and development of relugolix and MVT-602 previously conducted by Takeda. If Takeda did not conduct this research and development in compliance with applicable requirements, it could result in increased costs and delays in our development of these product candidates.

Prior to our acquisition of worldwide rights (excluding Japan and certain other Asian countries) to relugolix and worldwide rights to MVT-602, we had no involvement with or control over the nonclinical or clinical development of relugolix or MVT-602. We are dependent on Takeda having conducted such research and development in accordance with the applicable protocols, legal, regulatory, and scientific standards, having accurately reported the results of all clinical studies and other research conducted prior to our acquisition of the rights to relugolix and MVT-602, having correctly collected and interpreted the data from these studies 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 assets. Problems related to any of such nonclinical or clinical work could result in increased costs and delays in the development of our product candidates, which could adversely affect our ability to generate any future revenue from these product candidates.

Recruitment, enrollment and retention of patients in clinical studies is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical studies on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to satisfactorily complete any of our clinical studies. Enrollment in our clinical studies may be slower than we anticipated, leading to delays in our development timelines. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, the nature of the study protocol, our ability to recruit clinical study investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical studies of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the study and the proportion of patients screened that meet those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical studies will not comply with the protocol or will drop out of the studies before completion. In addition, unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the COVID-19 pandemic, in or around the

countries in which we conduct our clinical studies, could delay the commencement or rate of completion of our clinical studies. Furthermore, any negative results we or a collaboration partner may report from clinical studies of our product candidates may make it difficult or impossible to recruit, enroll, and retain patients in other clinical studies of that same product candidate. Similarly, negative or positive results reported by our competitors about their products or product candidates may negatively affect patient recruitment, enrollment, or retention in our clinical studies. Also, marketing authorization of competitors in the same class of product candidates may impair our ability to recruit, enroll, or retain patients into our clinical studies, delaying or potentially preventing us from completing clinical studies. Delays or failures in planned patient recruitment, enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.

Even if our clinical studies are completed as planned, we cannot be certain that their results will support the efficacy or safety of our product candidates. For example, product candidates may not meet the criteria for success for their primary endpoint specified in the statistical analysis plan, highlighting the importance of appropriate selection of the primary endpoint, statistical powering of a clinical study, and diligent oversight of the treatment compliance of those patients enrolled into the study. Success in nonclinical testing and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of later clinical studies will replicate the results of prior clinical studies and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical study as a whole will be successful. In addition, the FDA may not agree that clinical study results are sufficient for approval for any product candidate, or even if approved, may not support a label that is capable of competing with existing treatments. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical studies, even after having achieved promising results in earlier nonclinical or clinical studies. These setbacks have been caused by, among other things, nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Positive results from any of our clinical studies may not be predictive of the results of any of our other ongoing and potential future clinical studies, and there can be no assurance that the results of studies conducted by third parties will be viewed favorably or are indicative of our own future study results. We may publicly disclose top-line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review, audit, and verification of the data related to the particular study. We 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 top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated.

A future failure of a clinical study to meet its primary endpoints would likely cause us to abandon a product candidate and may delay development of a product candidate. Any delay in, or termination of, our clinical studies will delay the submission of our NDAs to the FDA or other similar applications to other foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate net product revenue.

Reported data or other clinical development announcements by Takeda, its partners or sublicensees, or by our collaboration partners, including Pfizer, Richter, or Accord may adversely affect our commercialization of our drug products and our clinical development plans.

Takeda, its partners and sublicensees, and our collaboration partners, Pfizer, Richter, and Accord may be involved in the further clinical development of relugolix. Favorable announcements by Takeda, Pfizer, Richter, or Accord do not guarantee that the results of our clinical studies will also be favorable as the designs of our clinical studies may differ from those of Takeda, Pfizer, Richter, or Accord. Further, if clinical study or post-marketing adverse events regarding relugolix are reported, or subsequent announcements by our partners regarding relugolix are unfavorable, it could negatively impact our commercialization of drug products, and our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. For example, Takeda has developed relugolix for the treatment of women with uterine fibroid-associated pain and heavy menstrual bleeding in Japan. Takeda reported positive top-line results from its two Phase 3 clinical studies in Japan in women with uterine fibroids and has obtained market authorization in Japan from the Ministry of Health, Labor and Welfare for Relumina® tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids, including heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia. We cannot provide assurance that the FDA or other health authorities will allow us to use the data from Takeda's clinical studies in support of any NDA or marketing authorization application that we may submit, and such data may be interpreted differently by the regulatory authorities and provide contradictory evidence in support of the FDA's (or other regulatory authority) evaluation. If the FDA or

other regulatory authorities do not allow us to use the data from Takeda's clinical studies, we may be required to perform additional clinical studies.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, our ability to generate net product revenue will be materially impaired.

We have invested and expect to continue to invest a substantial portion of our efforts and expenditures in the development and advancement of our product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries. We and our collaboration partners are not permitted to market our product candidates in the U.S. until we receive approval of NDAs or sNDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries. Obtaining approval of an NDA, an sNDA or similar foreign regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authority may delay, limit or deny approval of our product candidates. The time required to obtain approval of an NDA or an sNDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authority. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approvals may change during the course of a product candidate's clinical development and may vary among jurisdictions. Obtaining approval of an NDA or an sNDA from the FDA or a regulatory approval from a regulatory authority outside the U.S. is an expensive process. The submission of NDAs and sNDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under approved NDAs and sNDAs are also subject to annual program user fees. We may incur additional costs in the future for our anticipated regulatory submissions, including the fees associated with NDAs, sNDAs and foreign equivalent submissions.

Securing marketing approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of our product candidates for the specified indication. The process of responding to the FDA or other regulatory authorities' information requests in the review process, potentially preparing for and appearing at a public advisory committee or oral hearing, and preparing our manufacturers and investigators to successfully complete inspections by the FDA or other regulatory authorities during the approval process requires significant human and financial resources. If the information from our completed clinical studies is insufficient to support regulatory approvals, we may have to complete ongoing or additional clinical studies.

We rely on third-party CROs and consultants to assist us in submitting and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Delays or errors in the submission of applications for marketing approvals or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approvals, commercialize our product candidates, and generate net product revenue. Despite efforts at compliance, from time to time, we or our partners may receive notices of manufacturing, quality-related, or other observations following inspections by regulatory authorities, as well as official agency correspondence regarding compliance. We also face the risk that our CMOs may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If Excella or our other CMOs fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for our commercialization, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation, or other reasons, our development plans and commercialization of our product candidates could be significantly delayed or otherwise adversely affected.

Even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction which would limit our ability to realize our product candidates' full market potential.

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 for a product candidate by the FDA in the U.S. does not ensure approval by regulatory authorities in any other country or jurisdiction. In addition, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical studies 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 are reliant, in part, upon the regulatory expertise of Richter to gain approval for certain drug products in the licensed territories and are completely reliant on Richter to generate net product revenue in the territories

licensed to Richter. For example, in July 2021, the EC, and August 2021, the MHRA, approved RYEQO as the first and only long-term, once-daily oral treatment in the EU and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. In addition, in April 2022, the EC approved ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer. We will rely on Richter and Accord to successfully commercialize our approved drug products in Europe. If we or our collaboration partners 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.

Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Adverse events associated with our product candidates could cause us, regulatory authorities, or other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical studies for our product candidates, our ability to obtain regulatory approval or a desirable label for such product candidates may be negatively impacted. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

We are required to monitor the safety and efficacy of ORGOVYX, MYFEMBREE and RYEQO and any other product candidates that are approved by the FDA or other regulatory authorities. We are subject to ongoing regulatory requirements to submit safety and other post-marketing information and reports, including adverse event reporting. Post-marketing adverse events related to ORGOVYX and MYFEMBREE could negatively impact our commercialization plans for these products and could negatively impact the clinical development of our product candidates.

If any of our approved drug products cause, or any of our product candidates are approved and then cause, serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a Risk Evaluation and Mitigation Strategy (a "REMS") (or equivalent outside the U.S.) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to conduct post-marketing studies or clinical studies;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or limit the duration of use;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may be required to repeat a nonclinical or clinical study or terminate a program, even if other studies or studies related to the program are ongoing or have been successfully completed;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing ORGOVYX, MYFEMBREE, and any of our product candidates, if approved.

Even though we have obtained regulatory approval for ORGOVYX and MYFEMBREE in the U.S., and RYEQO and ORGOVYX in Europe, or even if we obtain regulatory approval for any of our product candidates, we face or will still face extensive regulatory requirements and our products may face future development risks and regulatory difficulties.

Our drug products and any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, and promotional activities for such product, among other things, are and will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping, and cGCP requirements for any clinical studies that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions-including in some cases, a boxed warning, be included in the product labeling. Even if any product candidate receives marketing approval, if the indication approved by regulatory authorities is narrower than we expect or the accompanying label limits the approved use of our product, our sales of products could be limited, and we may not generate significant revenue from sales of our products.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA does not regulate the behavior of physicians in their choice of treatments and physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. However, regulatory authorities, including the FDA, impose stringent restrictions on manufacturers' communications regarding off-label use of their products, and if regulatory authorities believe that we are in violation of these restrictions, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the U.S., and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorney Generals, and other foreign regulatory agencies alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements may yield various results, including those discussed in the Risk Factor titled, "Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval."

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payers, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers, patient support service providers, charitable organizations, and customers may 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 for which we obtain marketing approval. Such laws include, among others, the federal Anti-Kickback Statute, the federal false claims laws, HIPAA, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, the federal Physician Payments Sunshine Act, and analogous state fraud and abuse, data privacy, and transparency laws. For a more detailed discussion of the healthcare laws that may affect our business, see "Other Healthcare Laws and Compliance Requirements" in Part I, Business Section, of this Annual Report.

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 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, imprisonment, possible exclusion from participation in Medicare Part D, Medicaid, and other federal healthcare programs or similar programs in other countries or jurisdictions, 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 to resolve allegations of non-compliance with these laws, 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 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 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.

Changes in legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize our drug products or product candidates and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug products in other jurisdictions or product candidates in the U.S. and other jurisdictions, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. In the U.S., such scrutiny has resulted in several Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Congress is considering additional health reform measures. For a more detailed discussion of the healthcare reform measures that may affect our business, see “Healthcare Reform” in Part I, Business Section, of this Annual Report.

At the state level, individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or other agency regulations, guidance or interpretations will be changed, or what the impact of such changes on our current and future operations, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Dependence on Third Parties

We are dependent upon our relationships with collaboration partners to further develop, fund, manufacture, and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer collaborate to jointly develop and commercialize relugolix in oncology and women’s health in the Co-Promotion Territory. In addition to the Pfizer Collaboration and License Agreement, we have entered into collaboration arrangements with other collaboration partners. On August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion pursuant to which, among other things, Sunovion has agreed to provide to us certain market access services with respect to the distribution and sale of ORGOVYX for prostate cancer, MYFEMBREE for uterine fibroids, and MYFEMBREE for endometriosis, if approved, in the U.S. On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which, among other things, Richter will be responsible for all commercialization activities for RYEQO for the treatment of women with uterine fibroids and relugolix combination tablet for endometriosis (if approved) in certain territories outside of the U.S. On May 5, 2022, we entered into the Accord License Agreement pursuant to which, among other things, Accord will be responsible for all commercialization activities of ORGOVYX in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa and India.

We are subject to a number of risks associated with our dependence on our relationships with our collaboration partners, including:

- our collaboration partners may terminate their collaboration agreements with us for reasons specified in the collaboration agreements, including our breach;
- the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration partners in the event that a collaboration partner was to terminate its collaboration with us;
- adverse decisions by a collaboration partner regarding the amount and timing of resource expenditures for the commercialization, distribution, and sale of our drug products;
- failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the collaboration agreement with us);
- failure by a collaboration partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;
- collaboration partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or products candidates; for example, Accord Healthcare Ltd. is our collaboration partner responsible for the commercialization of ORGOVYX in Europe and one of its affiliates, Accord BioPharma (U.S.) sells Camcevi™, a competitive drug to ORGOVYX, in our U.S. market;
- decisions by a collaboration partner to prioritize other of its current or future products more highly than our drug products or our product candidates when it performs its duties;
- possible disagreements with a collaboration partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and
- the financial returns to us, if any, under our collaboration agreements with Pfizer, Richter, and Accord depend in large part on the achievement of milestones and generation of product sales, and if Pfizer, Richter, or Accord fail to perform or satisfy their obligations under the collaboration agreements, the development and commercialization of our drug products could be delayed, hindered or may not occur and our business and prospects could be materially and adversely affected.

Due to these factors and other possible disagreements with our collaboration partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration partner were to terminate our collaborative relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense, and/or seek one or more other partners for some or all of these activities in the U.S. or worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates, and could prevent us from effectively commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration partners.

Regulatory requirements or manufacturing disruptions may make it difficult for us to be able to obtain materials or supplies necessary to conduct clinical studies or to manufacture and sell any of our product candidates, if approved.

To sustain our business, we need access to sufficient quantities of our product candidates to satisfy our clinical study needs and, if approved, to maintain sufficient commercial inventories of our products. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture commercial products would be limited.

Suppliers of key components and materials must be named in the NDA or marketing authorization application filed with the FDA, the EMA, or other regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if those suppliers are not approved or the qualification of a new supplier is required. If these third

parties do not perform as we expect, do not maintain their regulatory approvals or become subject to other negative circumstances, it may result in a delay in our ability to obtain approvals from the FDA or other regulatory authorities. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money, and effort in the area of production and quality control to ensure full compliance with cGMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities both prior to and following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations, issue import restrictions or other cGMP or regulatory action that could affect our ability to obtain materials from such supplier. If the manufacturing operations of any single suppliers for any of our products are adversely affected or suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet demand, which could harm our business. In addition, if delivery of materials from our suppliers was interrupted for any reason, we may be unable to ship commercial products that may be approved for marketing or supply our products in development for clinical studies. In addition, some of our products and the materials that we utilize in our operations are made only at one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers we depend on, including in the event of a disaster, including an earthquake or a pandemic, equipment failure or other difficulty, may negatively impact our development and commercialization efforts. If we were to encounter any of these difficulties, our ability to provide our products, if approved, and product candidates to patients would be jeopardized.

We are reliant on third parties to conduct, manage, and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We currently do not have the ability to independently conduct nonclinical studies that comply with Good Laboratory Practice ("GLP") requirements. We rely substantially on CROs and clinical study sites to ensure the proper and timely conduct of our clinical studies, and we have limited influence over their actual performance.

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with current GLP and GCP regulations and guidelines enforced by the FDA and are also required by the competent authorities of the member states of the European Economic Area and comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our product candidates that are in nonclinical and clinical development, respectively. The regulatory authorities enforce GCP regulations through periodic inspections of clinical study sponsors, CROs, and clinical study sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our nonclinical studies and clinical studies is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we, our CROs or clinical study sites fail to comply with current GCP requirements, the clinical data generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical studies before approving our marketing applications. Accordingly, if we or 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 studies, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as the sponsor of those studies.

While we have agreements governing their activities, our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future 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 studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation 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 (or their own) clinical protocols or regulatory requirements or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase, and our ability to generate revenue could be delayed.

In addition, we and our CROs are subject to various data privacy laws in the U.S., Europe, and elsewhere that are often uncertain, contradictory, and evolving. It is possible that these data privacy laws may be interpreted and applied inconsistent with our or our CROs practices. If so, this could result in government-imposed fines or orders requiring that we or our CROs change our practices, which could adversely affect our business. Also, see the Risk Factor titled, "If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance."

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 materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our 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.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our drug development programs, products, and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to relugolix, MVT-602, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our development programs and product candidates. 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.

The patent applications that we own or have in-licensed may fail to result in issued patents with claims that protect relugolix, MVT-602 or any future product candidate in the U.S. or in other foreign countries. 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 a patent. Even if patents do successfully issue and even if such patents cover relugolix, MVT-602 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. 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 product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs, products, and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for relugolix, MVT-602 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO") or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference

proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or 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. 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 product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. 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 products similar or identical to ours.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We have licensed certain intellectual property rights covering our current products and product candidates from Takeda. If, for any reason, the Takeda License Agreement is terminated or we otherwise lose those rights, it could adversely affect our business. The Takeda License Agreement imposes, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Our collaborations with Pfizer, Richter, and Accord also contain provisions for the assignment of, or a license to us for, intellectual property rights arising out of those agreements.

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 for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. 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. Noncompliance 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 application, 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 relugolix, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development of our product candidates and commercialization of our drug products and any future product candidate.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as

well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign 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 and market exposure as a public company, 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.

Also, 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. 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 patent rights in the future and claim that use of our technologies infringes upon rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such products or 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 products or product candidates 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. 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.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or 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 us, 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, 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 product candidates, and we may do 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 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 or other forms of compensation to third parties.

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

Competitors may infringe 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 legal claims, which can be expensive and time consuming. In addition, 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. 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 and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, enablement, written description, or patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution.

Third parties may also raise similar validity claims before the USPTO in post-grant proceedings, such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware

during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our products, or current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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

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.

The U.S. has enacted and implemented wide-ranging patent reform legislation. 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. 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, 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 may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering relugolix, MVT-602, and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

In addition, the ongoing conflict in Ukraine and related sanctions could significantly devalue our patents and patent applications in Ukraine, the Russian Federation and certain other countries and regions, such as Belarus and Eurasia. The ongoing conflict in Ukraine, the recent Russian decrees and other countries' sanctions against the Russian Federation may also significantly limit our ability to enforce our patents in Ukraine, the Russian Federation, and certain other countries. We cannot predict when or how this situation will change.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our drug products and other clinical study materials, and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, MVT-602, and any future 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 partnerships, market access, distribution 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. 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. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, 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 discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Being a Controlled Company

We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

There are a number of relationships that may give rise to certain conflicts of interest between Sumitovant and Sumitomo Pharma, and their affiliates, on the one hand, and the other investors of our common shares and us, on the other hand. We are party to a loan agreement with Sumitomo Pharma that creates restrictions, including limiting or restricting our ability to take specific actions, such as raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends. In addition, we are party to an Investor Rights Agreement with Sumitovant and Sumitomo Pharma that, although designed in part to provide protections for our minority shareholders, also provides rights to Sumitovant and Sumitomo Pharma, such as the ability of Sumitomo Pharma to appoint directors on our board, to maintain their share ownership percentage in our company, and (together with an information sharing agreement we have with Sumitovant) to provide Sumitovant with certain information and give them access to certain of our records. Further, we are a party to a Market Access Services Agreement with Sunovion, a subsidiary of Sumitomo Pharma, pursuant to which Sunovion provides certain market access services with respect to the distribution and sale of ORGOVYX and MYFEMBREE in the U.S. We may enter into additional agreements with Sumitovant or Sumitomo Pharma or their affiliates in the future. Sumitovant and Sumitomo Pharma and its affiliates may have interests which differ from our interests or those of the minority holders of our common shares. Any material transaction between us and Sumitomo Pharma and its affiliates is subject to our related party transaction policy and the Investor Rights Agreement, which requires prior approval of such transaction by our Audit Committee composed of three independent directors. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to conduct business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows, and on the market price of our common shares. Further, our agreements with Sumitovant, Sumitomo Pharma and Sunovion may result in unanticipated risks or other unintended consequences on our business and on investor perception that could have a significant impact on the market price of our common shares.

We are a "controlled company" within the meaning of the applicable rules of the New York Stock Exchange ("NYSE") and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, our shareholders will not have the same protections afforded to shareholders of companies that are subject to such requirements.

We are currently a "controlled company" within the meaning of the NYSE corporate governance requirements. Under these rules, a "controlled company" may elect not to comply with certain corporate governance requirements. We have elected to use certain of these exemptions and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to shareholders of companies that are subject to all of the NYSE corporate governance requirements.

Risks Related to Us and Our Shareholders Related to Our Being a Foreign Corporation

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for our shareholders 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 in which 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, in which an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

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

There are regulatory limitations on the ownership and transfer of our common shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes the NYSE. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments, and our other securities to persons resident and non-resident for exchange control purposes without 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 NYSE or another appointed stock exchange.

Legislation enacted in Bermuda as to economic substance may affect our operations.

Pursuant to the Economic Substance Act 2018 of Bermuda, as amended (the "Economic Substance Act") that came into force on January 1, 2019, a registered entity other than an entity which is resident for tax purposes in certain jurisdictions outside Bermuda (a "non-resident entity") that carries on as a business any one or more of the "relevant activities" referred to in the Economic Substance Act must comply with economic substance requirements. The Economic Substance Act may require in-scope Bermuda entities which are engaged in such "relevant activities" to be directed and managed in Bermuda, have an adequate level of qualified employees in Bermuda, incur an adequate level of annual expenditure in Bermuda, maintain physical offices and premises in Bermuda or perform core income-generating activities in Bermuda. The list of "relevant activities" includes carrying on any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service centre, intellectual property and holding entities.

Based on the Economic Substance Act currently, for so long as we are a non-resident entity, we are not required to satisfy any such economic substance requirements other than providing the Bermuda Registrar of Companies annually information on the jurisdiction in which it claims to be resident for tax purposes together with sufficient evidence to support that tax residence. We currently do not anticipate material impact on our business or operations from the Economic Substance Act. However, since such legislation is new and remains subject to further clarification and interpretation, it is not currently possible to ascertain the precise impact of the Economic Substance Act on us. If we ceased to be a non-resident entity, we may be unable to comply with

the Economic Substance Act or may have to restructure our business to comply with the Economic Substance Act, either of which may have a material adverse effect on our business.

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

We are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. 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 when 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. Any such additional tax liability could 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. We currently have subsidiaries in the U.K., Switzerland, Ireland, and the U.S. 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 tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. In addition, our effective tax rate could be adversely affected if we do not obtain favorable tax rulings from certain taxing authorities. 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. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income 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, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

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 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 resulting from the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting as well as other initiatives led by the Organisation for Economic Co-operation and Development or the European Commission. 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 share-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in U.S. generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

U.S. holders that own 10% or more of the vote or value of our common shares may suffer adverse tax consequences because we and our non-U.S. subsidiaries are expected to be characterized as "controlled foreign corporations" ("CFCs"), under Section 957(a) of the U.S. Internal Revenue Code of 1986, as amended (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 (directly or indirectly), 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 vote 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 and our non-U.S. subsidiaries were classified as CFCs in the taxable year ended on March 31, 2022. For any U.S. holders who hold 10% or more of the vote or value of our common shares directly or indirectly, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder's share of our accumulated non-U.S. earnings and profits (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 U.S. Internal Revenue Service ("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. holder that is a U.S. corporation. Failure to comply with these reporting and tax paying obligations may subject such U.S. holder to significant monetary penalties and may prevent the statute of limitations from starting with respect to such U.S. holder's U.S. federal income tax return for the year for which reporting was due. If you are a U.S. holder who holds 10% or more of the vote or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing our common shares.

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

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the 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 ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and 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, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares. 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, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. With respect to the taxable year that ended on March 31, 2022, we believe that we were not a PFIC. However, we cannot predict whether we will or will not be classified as a PFIC in future taxable years because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of

our income and assets, which cannot be known at this time. Because the determination of whether we are a PFIC for any taxable year is a fact-intensive determination made annually after the end of each taxable year, and because certain aspects of the PFIC rules are uncertain, we cannot provide any assurances regarding our PFIC status for the current or future taxable years.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC.

General Risk Factors

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations.

To the extent that we raise additional funds by issuing equity or convertible debt securities, our existing shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of 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 raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends.

Our future success depends on our ability to attract and retain key personnel.

We expect to hire additional employees. The market for talent in our industry is very competitive. Many of the other pharmaceutical companies we compete against for qualified personnel have greater financial and other resources, more favorable risk profiles and a longer operating history in the pharmaceutical industry than we do. 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 than what we have to offer. It is particularly difficult to recruit and hire new employees during the COVID-19 pandemic as conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity.

In addition, our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the skills and leadership of our management team and key employees. Our senior management and key employees may terminate their positions with us at any time. If we lose one or more members of our senior management team or key employees or unable to attract and retain other personnel to accomplish our business objectives, our ability to successfully implement our business strategies could be seriously harmed.

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

We expect to continue to expand our organization and hire additional employees. Our management is expected to have increasing responsibilities to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors which may divert a disproportionate amount of its time and attention away from our day-to-day activities. The expected growth may also divert financial resources from other projects. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow net product revenue could be adversely affected, and we may not be able to implement our business strategies. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize our product candidates or any potential future product candidate may be adversely affected.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and could impact ongoing and planned clinical studies as well as limit commercialization of any products that we may develop.

The use of any of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by regulatory or governmental agencies, consumers, healthcare providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products or product candidates. On occasion, large monetary judgments have been awarded in class action lawsuits in which drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liabilities and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- inability to commercialize our products or any future products;
- impairment of our business reputation and significant negative media attention;

- withdrawal of participants from our clinical studies;
- significant costs to defend related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products or any future products, if approved for commercial sale; and
- loss of net product revenue.

The product liability and clinical study insurance we currently carry, and any additional product liability and clinical study 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 commercially reasonable terms or in adequate amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our common share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Use of social media platforms presents risks of inappropriate or harmful disclosures which could harm our business.

We believe that our potential patient population is active on social media. Social media practices in the pharmaceutical and biotechnology industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product or a product candidate, which could result in reporting obligations. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us, our products, or our product candidates on any social media platform. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

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 other biotechnology or pharmaceutical companies. 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 assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors 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 patents. 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. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our operating results may fluctuate significantly and our future operating results could fall below expectations. The market price of our common shares has been and is likely to continue to be highly volatile, and you may lose some or all of your investment.

The market price of our common shares has been and is likely to continue to be highly volatile and may be subject to significant fluctuations in response to a variety of factors. Our quarterly and annual operating results may fluctuate significantly in the future. Any future net product revenue will depend on the successful commercialization and sales of our drug products and product candidates that receive marketing approval. Any future regulatory milestones, sales milestones and royalty payments we are eligible to earn under the terms of our collaboration agreements with Pfizer, Richter, Accord, or any potential future collaboration and license agreements, if any, will depend on the achievement of the underlying milestone event or level of sales activity. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- the price, level of demand, and net revenues for our products, which may vary significantly as they are launched and compete for position in the marketplace;

- the extent to which coverage and adequate reimbursement is available from government and private payers such as Medicare Part D, Medicaid, the Department of Veterans Affairs, the Department of Defense, pharmacy benefit managers, health plans, self-insured organizations, insurance companies and other plan administrators with respect to our drug products and product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our approved products and our product candidates;
- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding, if needed, or funding on desirable terms;
- any delay in the commencement, enrollment, and ultimate completion of our clinical studies;
- actual or anticipated results of clinical studies of any of our product candidates or those of our competitors;
- any delay in submitting an NDA or similar application for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;
- failure to successfully develop and commercialize any of our current or future product candidates;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to any of our products or current or future product candidates;
- adverse regulatory decisions or findings;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for any of our products or current or future product candidates, or the inability to do so at acceptable prices;
- inability to maintain a qualified sales force;
- inability to establish and maintain commercial capabilities and expertise including product marketing, sales, trade and distribution, pricing, market access, data analytics and insights, and other commercial operations functions;
- adverse developments or perceived adverse developments with respect to vendors on which we rely, including CMOs, CROs and third-party logistics providers;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to maintain effective internal control over financial reporting;
- failure to meet or exceed the estimates and projections of the investor community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations on us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- adverse developments or perceived adverse developments with respect to our manufacturing, collaboration and alliance partners and affiliates, including Takeda, Excella, Sumitovant, Sumitomo Pharma, Sunovion, Pfizer, Richter, and/or Accord;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of our management or other key personnel;

- short sales of our common shares;
- sales or purchases of a substantial number of our common shares in the public market, by any of our significant shareholders, or the perception in the market that the holders of a large number of our common shares intend to sell or purchase common shares;
- sales or purchases of our common shares by our executive officers or members of our board of directors;
- issuance of additional shares of our common shares, or the perception that such issuances may occur;
- negative coverage in the media or securities analyst reports, whether accurate or not;
- any changes in our relationships with Sumitomo Pharma, Sumitovant, Sunovion and/or their respective affiliates, or actions taken or omission of actions with respect to the Sumitomo Pharma Loan Agreement, the Investor Rights Agreement, the Market Access Services Agreement or under the other agreements we entered with Sumitomo Pharma, Sumitovant, Sunovion and their respective affiliates;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- trading liquidity of our common shares;
- investors' general perception of our company, our business, and our majority shareholder;
- various social, political, economic, industry, and market conditions in the U.S. and around the world (including wars and other forms of conflict, such as the conflict in Ukraine);
- effects of natural or man-made catastrophic events, including the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or securities analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the public, or if the forecasts we provide to the public are below the expectations of securities analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

If we are unable to maintain proper and effective internal control over financial reporting and disclosure controls and procedures, investor confidence in our company and, as a result, the value of our common shares, may be adversely affected.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act to assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, we are also required to include in this Annual Report an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. If we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. If our disclosure controls and procedures are ineffective in the future, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our

reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline.

Volatility in our common share price could subject us to securities class action litigation.

Stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common shares, regardless of our actual operating performance.

Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings, if any, for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. We are also subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments. Additionally, our ability to pay dividends is currently restricted by the terms of the Sumitomo Pharma Loan Agreement. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, United Kingdom SW1Y 4LB. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. We also have business operations in Brisbane, California and Basel, Switzerland. We do not own any properties.

We lease 40,232 square feet of office space located in Brisbane, California, pursuant to a lease agreement that expires in May of 2026, for which we have the option to extend the lease term for an additional seven years. We also sublease 20,116 square feet of office space pursuant to a sublease agreement that expires in February of 2024. We believe that our 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 proceedings related to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results, or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Shares

Our common shares trade on the New York Stock Exchange ("NYSE") under the symbol "MYOV."

Shareholders

American Stock Transfer & Trust Company is the transfer agent and registrar for our common shares. As of May 6, 2022, we had three shareholders of record of our common shares. The number of beneficial owners of our common shares at that date was substantially greater. The number of holders of record is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid cash dividends on our common shares. We currently anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate declaring or paying cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on a number of factors, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. In addition, pursuant to Bermuda law, a company may not declare or pay dividends if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due or (2) that the realizable value of its assets would thereby be less than its liabilities. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the Sumitomo Pharma Loan Agreement.

Recent Sales of Unregistered Securities

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Objective

The purpose of the following discussion and analysis is to provide material information relevant to an assessment of our financial condition and results of operations from management's perspective, including to describe and explain key trends, events, and other factors that impacted our reported results for the periods presented and that are reasonably likely to impact our future performance.

The discussion and analysis below is organized as follows:

- executive summary, including a description of our business and significant events that are important to understand our results of operations and financial condition;
- a description of the components of our results of operations and a discussion of our results of operations, including an explanation of significant changes between the periods presented in the specific line items of our statements of operations;
- financial condition addressing our liquidity position, sources and uses of cash, capital resources and requirements, and commitments; and
- critical accounting policies and significant judgments and use of estimates which are most important to our financial condition and results of operations.

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") should be read in conjunction with our audited consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K ("Annual Report"). The following discussion contains forward-looking statements and should also be read in conjunction with the cautionary statement set forth at the beginning of this Annual Report.

This section generally discusses our financial results for the fiscal years ended March 31, 2022, and 2021 and comparisons between these fiscal years. A discussion of our financial results for the fiscal year ended March 31, 2020 and a comparison between the fiscal year ended March 31, 2021 and the fiscal year ended March 31, 2020 that are not included in this Annual Report can be found under Item 7 of Part II of our Annual Report on Form 10-K for the year ended March 31, 2021, filed with the United States Securities and Exchange Commission ("SEC") on May 11, 2021, which is available free of charge on the SEC's website at www.sec.gov and our investor relations website at investors.myovant.com.

Business Overview

We are a biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. by the U.S. Food and Drug Administration ("FDA") in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; and (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and United Kingdom ("U.K."), respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In April 2022, the EC approved ORGOVYX (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. In September 2021, the FDA accepted to review our supplemental New Drug Application ("sNDA") for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. On May 6, 2022, we and Pfizer announced that the FDA extended the Prescription Drug User Fee Act ("PDUFA") goal date for this sNDA to August 6, 2022. MYFEMBREE is being evaluated for contraceptive efficacy in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy. We are also developing MVT-602, an investigational oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from the upfront and milestone payments we have received from our collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S.,

and to a lesser extent from revenues generated from sales of product supply to Gedeon Richter Plc. ("Richter") as well as royalties on net sales of RYEQO in Richter's Territory.

Our majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma"), the name of which prior to April 1, 2022 was Sumitomo Dainippon Pharma Co., Ltd. As of March 31, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, own 50,041,181, or approximately 52.8%, of our outstanding common shares.

Year Ended March 31, 2022 Financial Highlights and Recent Business Updates

In this section, we summarize certain of our year ended March 31, 2022 financial highlights and recent regulatory, clinical and business updates. Additional information about our business, our approved products, and our product candidates is included in Part I, Item 1., "Business," of this Annual Report.

Financial Highlights

- Total revenues for the year ended March 31, 2022, were $231.0 million compared to $59.3 million for the year ended March 31, 2021.
- Product revenue, net for the year ended March 31, 2022, was $94.3 million, compared to $3.6 million for the year ended March 31, 2021. Net revenue from sales of ORGOVYX and MYFEMBREE were $83.0 million and $6.4 million, respectively, for the year ended March 31, 2022.
- Selling, general, and administrative ("SG&A") expenses for the year ended March 31, 2022, were $259.4 million, compared to $181.4 million for the year ended March 31, 2021.
- Research and development ("R&D") expenses for the year ended March 31, 2022, were $107.4 million, compared to $136.7 million for the year ended March 31, 2021.
- Net loss for the year ended March 31, 2022, was $206.0 million, or $2.22 per common share, compared to a net loss of $255.1 million, or $2.83 per common share, for the year ended March 31, 2021.
- Cash, cash equivalents, and marketable securities were $434.2 million at March 31, 2022, compared to $684.9 million at March 31, 2021.

See "Results of Operations" below for a discussion of our results of operations for the year ended March 31, 2022, as compared to the year ended March 31, 2021.

Recent Business Updates

Regulatory

- On May 6, 2022, we and Pfizer announced that the FDA extended the PDUFA goal date to August 6, 2022 for the sNDA for MYFEMBREE for the management of moderate to severe pain associated with endometriosis to allow time to review additional analyses related to bone mineral density submitted in response to the FDA's information request. No new clinical data was requested by the FDA. The submission of the additional analyses has been determined by the FDA to constitute a Major Amendment to the sNDA, resulting in an extension of the PDUFA goal date.
- On April 29, 2022, the EC approved ORGOVYX as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe.
- On March 29, 2022, one of our subsidiaries, Myovant Sciences GmbH ("MSG"), submitted an sNDA to the FDA that included the two-year data from the Phase 3 LIBERTY randomized withdrawal study.
- On July 16, 2021, the EC, and on August 9, 2021, the MHRA, approved RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age in the EU and U.K., respectively. RYEQO is the first and only long-term, once-daily oral treatment for uterine fibroids with no limitation on its duration of use approved in the EU and the U.K. Richter, our commercialization partner for RYEQO in Europe and certain other international markets, has launched RYEQO in 17 countries since these regulatory approvals. The approval of RYEQO in the EU triggered a $15.0 million regulatory milestone payment from Richter, which we received in the three months ended September 30, 2021.
- On May 26, 2021, the FDA approved MYFEMBREE as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids. MYFEMBREE was launched in the U.S. for this indication by us and our collaboration partner, Pfizer, in June 2021. The FDA approval of MYFEMBREE for this indication triggered a $100.0 million regulatory milestone payment from Pfizer, which we received in the three months ended September 30, 2021.

Clinical

- In October 2021, we and Pfizer presented data from clinical studies of MYFEMBREE at the American Society for Reproductive Medicine ("ASRM") 2021 Congress, including results of the Phase 3 LIBERTY randomized withdrawal study, which was designed to evaluate the efficacy and safety of relugolix combination therapy for up to two years in women with heavy menstrual bleeding associated with uterine fibroids, and was designated an ASRM Prize Paper. Additional data presentations at the ASRM 2021 Congress included data from the SPIRIT 1 and SPIRIT 2 studies of women with pain associated with endometriosis as well as pooled safety and tolerability data from the LIBERTY and SPIRIT clinical programs.

- In May 2021, the FDA informed us that they placed a partial clinical hold on the Phase 3 SERENE study evaluating MYFEMBREE for the prevention of pregnancy, pending certain study protocol modifications. In August 2021, the FDA informed us that the partial clinical hold for the Phase 3 SERENE study was lifted following study protocol amendments. The primary analysis of the study, prevention of pregnancy, remains unchanged, but now the SERENE study will only evaluate women with a confirmed diagnosis of uterine fibroids or endometriosis. Bone mineral density monitoring will occur throughout the treatment period as well as after treatment is discontinued to gain additional insights into bone health, which will augment the safety profile observed in the LIBERTY and SPIRIT programs. The enrollment target was increased to 1,020 patients who are 18 to 50 years of age and at risk for pregnancy, enhancing the power of the study. Patient screening with this updated protocol began in September 2021, with initial patients dosed in October 2021.

- Data from the SPIRIT long-term extension study demonstrated clinically meaningful improvements in dysmenorrhea (84.8% of patients) and non-menstrual pain (75.8% of patients) over two years in women with endometriosis-associated pain. The safety profile during the second year of treatment, including bone mineral density, was consistent with that observed during the first year with no new safety signals identified.

Intellectual Property

- On June 15, 2021, the United States Patent and Trademark Office ("USPTO") granted U.S. Patent. No. 11,033,551 to Myovant. This patent covers the unique and innovative method of treating patients for heavy menstrual bleeding associated with uterine fibroids with MYFEMBREE. This patent will expire in September of 2037 and is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). This patent term matches that of two methods patents (U.S. Patent. Nos. 10,786,501 and 10,449,191) previously granted by the USPTO for ORGOVYX that cover methods of treating advanced prostate cancer with relugolix.

Business Development

- On May 5, 2022, one of our subsidiaries, MSG, entered into an exclusive license agreement (the "Accord License Agreement") with Accord Healthcare, Ltd. ("Accord") and Intas Pharmaceuticals, Ltd., parent entity of Accord, for Accord to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX (relugolix 120 mg) in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa, and India. We are entitled to receive an upfront payment of $50.0 million, which we expect to receive in the three months ending June 30, 2022. We are also eligible to receive up to $90.5 million in commercial launch, sales-based, and other milestones. In addition, we are eligible to receive tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's territories. See section titled "Our Key Agreements" set forth in Part I. Item 1. for additional information about the Accord License Agreement.

Management and Board of Director Appointments

- Effective on November 5, 2021, Dr. Nancy Valente, M.D. was appointed by Myovant's Board as an independent director following Ms. Kathleen Sebelius' retirement from Myovant's Board. Dr. Valente also became a member of the Audit Committee and the Chair of the Nominating and Corporate Governance Committee of Myovant's Board.

- On September 7, 2021, Uneek Mehra was appointed Chief Financial and Business Officer of Myovant Sciences, Inc. Concurrent with this appointment, Mr. Mehra was also appointed Principal Financial Officer of Myovant Sciences Ltd. Mr. Mehra succeeds Frank Karbe, who left our company in August 2021.

- On April 5, 2021, we announced the appointment of Lauren Merendino as Chief Commercial Officer of Myovant Sciences, Inc.

Expected Upcoming Milestones

The following is a summary of certain of our expected upcoming milestones.

- We expect the FDA decision for the MYFEMBREE sNDA seeking approval for the management of moderate to severe pain associated with endometriosis by its extended PDUFA goal date of August 6, 2022. FDA approval would trigger a $100.0 million milestone payment from Pfizer. If approved by the PDUFA goal date, we and Pfizer expect to launch MYFEMBREE in the U.S. in endometriosis in August 2022. This indication would utilize the same dosage, formulation, administration, and branding as MYFEMBREE that was previously approved by the FDA in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids.

- We expect to present additional details around two-year data from the SPIRIT long-term extension study at a scientific conference in mid-calendar year 2022.

- We expect our commercialization partner, Accord, to launch ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe in the second half of calendar year 2022.

- We expect the European Medicines Agency regulatory submission for RYEQO for the treatment of women with endometriosis-associated pain in calendar year 2022. Richter will be the sponsor.

- We expect to submit New Drug Submissions to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer, MYFEMBREE for heavy menstrual bleeding associated with uterine fibroids, and MYFEMBREE for the treatment of endometriosis-associated pain in Canada in calendar year 2022.

Effects of the COVID-19 Pandemic on our Business

We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business. Our priorities during the COVID-19 pandemic have been to protect the health and safety of our employees, patients and healthcare providers while continuing our mission to redefine care through differentiated solutions in high unmet need areas within women's health and hormone-sensitive oncology. We believe the safety measures we have taken in response to the COVID-19 pandemic meet or exceed the guidelines established by government and public health officials. Most of our employees worked remotely during much of 2020 and 2021, and many of our employees continue to do so on a part-time or full-time basis, which required us to devise new ways of working and collaborating, including adopting remote working tools to minimize the disruption to our business activities. In April 2022, we reopened our offices, and our employees began to return to work onsite on a voluntary basis with specific safety protocols, including requiring vaccination as a condition of employment, subject to medical and religious exemptions, or as required by law. We have a distributed workforce, and our employees have become accustomed to working remotely and working with others who are working remotely for the past two years. However, as we reopen our offices, we may face operational or other challenges as we and our partners, customers, suppliers, vendors and other parties with whom we do business continue to adjust to a hybrid model of remote and onsite work. These challenges may result in operational inefficiencies, employee dissatisfaction, and distractions to management related to such transition, any of which could harm our business.

As of the date of this Annual Report, we do not believe that the COVID-19 pandemic has disproportionately impacted us relative to other companies in which we compete on our ability to advance our clinical studies, our regulatory activities, and our U.S. commercial launch activities for ORGOVYX and MYFEMBREE. We and our collaboration partner, Pfizer, commercially launched ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. To date, our partner, Richter, has launched RYEQO in 17 countries.

We believe that the COVID-19 pandemic continues to have an impact on our commercialization activities that is consistent with other companies in our industry. As a result of the COVID-19 pandemic, there have been changes in the practice of medical care and medical education. For example, many healthcare providers initially expanded their utilization of telemedicine to conduct patient visits, and in many regions of the U.S., the ability of commercial and medical affairs field teams to call on healthcare providers was restricted or converted to virtual access. Our oncology sales and medical affairs field teams resumed in-person interactions with healthcare providers in January 2021 and our women's health sales and medical affairs field teams began in-person interactions with healthcare providers in June 2021. Despite this, some physician's offices and many hospitals continue to have limited on-site access for pharmaceutical representatives in order to reduce exposure risk for their patients or staff. Conducting these interactions virtually could reduce the number of medical professionals we are able to engage with, limit our ability to engage with important staff members and virtual meetings have been shown to be less impactful than in-person meetings. The cancellation, postponement or virtual formats for medical conferences also limit access to physicians and reduce awareness of information shared at conferences (medical and promotional). In response to the COVID-19 pandemic, healthcare professionals may also reduce staffing and reduce or postpone appointments with patients, or patients may delay, cancel or miss

appointments, resulting in fewer prescriptions. Reduced access to healthcare providers may impact or require adjustments to our planned commercialization activities, including the manner in which our field teams engage with healthcare providers and facilities and supplementing field activities with additional marketing spend.

The COVID-19 pandemic also resulted in fewer opportunities for our medical affairs team to present scientific data as multiple medical conferences were canceled, postponed, or moved to virtual formats during 2020 and 2021, and for our regional medical advisors to engage potential prescribers in scientific exchange. Many conferences are planning to conduct in-person meetings in 2022, while continuing to offer virtual participation as an option. To date, we have not experienced supply constraints, and we believe we have procured sufficient quantities of relugolix drug substance to meet our U.S. ORGOVYX and MYFEMBREE launch plans.

Future developments regarding COVID-19 remain uncertain and the extent to which the COVID-19 pandemic ultimately impacts our business, financial condition or results of operations will depend on numerous factors, including the magnitude and duration of the pandemic, the distribution, acceptance and effectiveness of COVID-19 vaccines and treatments, the impact of new and potentially more virulent or transmissible variants of the coronavirus (e.g., the Delta and Omicron variants, respectively), the duration of governmental measures to mitigate the pandemic and how quickly and to what extent normal economic and operating conditions can resume, all of which remain uncertain and difficult to predict. Additionally, even after normalcy resumes, there will likely be some permanent changes to how healthcare is provided, how healthcare providers engage with our industry and perhaps how conferences are conducted. None of these changes can be anticipated at this point, nor can the potential impact on our business. As such, it is uncertain as to the full magnitude that the COVID-19 pandemic will have on our financial condition, liquidity, and future results of operations.

Refer to the risk factor titled “Business interruptions resulting from effects of pandemics or epidemics, such as the COVID-19 pandemic, may materially and adversely affect our business and financial condition,” as well as other risk factors included in the section titled “Risk Factors” set forth in Part I. Item 1A.

Effects of the Russian Federation-Ukraine Conflict on our Business

The uncertain nature, magnitude, and duration of hostilities stemming from the conflict in Ukraine, including the potential effects of sanctions, retaliatory cyber-attacks on the world economy and markets, and potential shipping delays, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business. As a result of the conflict in Ukraine, the U.S., U.K., and the EU governments, among others, have developed and coordinated economic and financial sanctions. As the conflict in Ukraine continues, there could be no certainty regarding whether such governments or other governments will impose additional sanctions, or other economic or military measures against the Russian Federation.

The impact the conflict in Ukraine, including economic sanctions or additional war or military conflict, as well as potential responses to them by the Russian Federation, is currently unknown and they could adversely affect our business, supply chain, clinical studies, suppliers or customers. In addition, the continuation of the conflict in Ukraine by the Russian Federation could lead to other disruptions, instability and volatility in global markets and industries that could negatively impact our operations. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, the availability and cost of raw materials and fuel, supplies, freight and labor, inflation, and fluctuations in currency exchange rates, all of which could impact our business, financial condition and results of operations.

Refer to the risk factor titled “The conflict between the Russian Federation and Ukraine and other government policies and actions could negatively affect our clinical trial sites in Ukraine. We and/or our collaboration partners may not be able to launch our commercial products in the Russian Federation, Ukraine or other regions which may negatively affect our or our collaboration partners’ financial results. The uncertain nature, magnitude, and duration of hostilities stemming from such conflict may result in changes in the world’s macroeconomic conditions which negatively affect our business operations.”

Certain Components of our Results of Operations

Revenues

We have two FDA-approved products that generate product revenue in the U.S: ORGOVYX and MYFEMBREE. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions. For the year ended March 31, 2022, the gross-to-net deduction for ORGOVYX was approximately 40%, and we expect it to be in the low-to-mid 40%’s for the foreseeable future. Product revenue, net also includes revenues related to product supply to Richter as well as royalties on net sales of RYEQO in Richter’s Territory.

Our Pfizer collaboration revenue consists of the partial recognition of the upfront payment and of the regulatory milestone payment that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids.

Our Richter license and milestone revenue consists of the recognition of the regulatory milestone payment that was triggered upon the EC approval of RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and the recognition of revenue associated with upfront and regulatory milestone payments we received from Richter pursuant to the terms of the Richter Development and Commercialization Agreement.

See Note 13 to our audited consolidated financial statements included elsewhere in this Annual Report for additional information regarding the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement.

Cost of Product Revenue

Our cost of product revenue is composed of the cost of goods sold and royalty expense payable to Takeda. Our cost of goods sold consists of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight, and indirect overhead costs associated with sales of ORGOVYX and MYFEMBREE in the U.S. and sales of product supply to Richter. The cost of inventories written down as a result of excess, obsolescence, or other reasons is also charged to cost of goods sold. Our royalty expense consists of royalties on net sales of relugolix payable to Takeda pursuant to the terms of the Takeda License Agreement (see Note 14(D) to our audited consolidated financial statements included elsewhere in this Annual Report).

As a result of the FDA approvals of ORGOVYX and MYFEMBREE, we subsequently began capitalizing inventories manufactured or purchased for each product after its respective approval date. As a result, we expensed certain manufacturing costs of ORGOVYX and MYFEMBREE as R&D expenses prior to FDA approval and, therefore, these costs are not included in cost of goods sold.

Collaboration Expense to Pfizer

Our collaboration expense to Pfizer consists of Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S. (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report).

Selling, General and Administrative Expenses

Our SG&A expenses consist primarily of personnel costs, including salaries, sales incentive compensation, bonuses, fringe benefits, and share-based compensation for our executive, finance, human resources, legal, information technology, commercial operations, marketing, market access, sales, and other administrative functions. Our SG&A expenses also include marketing programs, patient assistance and support programs for qualified uninsured and underinsured patients, promotion and advertising, conferences, congresses, travel expenses, professional fees for legal, accounting, auditing and tax services, and costs related to rent and facilities, insurance, information technology, commercial operations, and general overhead. Our SG&A expenses also include related party expenses pursuant to our agreements with Sunovion and Sumitovant (see Note 6 to our audited consolidated financial statements included elsewhere in this Annual Report).

SG&A expenses in fiscal year 2022 are expected to increase as compared to fiscal year 2021 due to increased marketing and promotional expenses to support the ongoing commercialization of ORGOVYX and MYFEMBREE in the U.S., including annualization of the MYFEMBREE marketing and promotional spend and targeted patient activation for both brands. The timing and magnitude of our SG&A expenses are primarily dependent on our commercial success and sales growth of ORGOVYX and MYFEMBREE, as well as the timing of any new indications or product launches and other potential business and operational activities. We expect that certain SG&A expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report).

Research and Development Expenses

R&D activities have been, and will continue to be, central to our business model. Our R&D expenses to date have been primarily attributable to the clinical development of our product candidates including the conduct of multiple Phase 3 and earlier clinical studies, the expansion of our team, and the initiation of activities in preparation for our anticipated commercial launches such as the establishment of our medical affairs function, as well as regulatory and certain manufacturing activities. Our R&D expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Our program-specific costs primarily include third-party costs, which include expenses incurred under agreements with CROs and CMOs, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, as well as costs related to pre-commercial manufacturing activities and regulatory submissions, and other third-party expenses directly attributable to the development of our product candidates.

Our unallocated R&D costs primarily include employee-related expenses, such as salaries, share-based compensation, fringe benefits and travel for employees engaged in R&D activities including clinical operations, biostatistics, regulatory, and medical affairs, and the cost of contractors and consultants who assist with R&D activities not specific to a program, and costs associated with nonclinical studies.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors that include, but are not limited to: the number of studies required for approval; the per patient study costs; the number of patients who participate in the studies; the number of sites included in the studies; the countries in which the studies are conducted; the length of time required to recruit and enroll eligible patients; the number of patients who fail to meet the study's inclusion and exclusion criteria; the number of study drug doses that patients receive; the drop-out or discontinuation rates of patients; the potential additional safety monitoring or other studies requested by regulatory agencies; the duration of patient follow-up; the timing and receipt of regulatory approvals; the costs of clinical study materials; and the efficacy and safety profile of the product candidate.

In addition, the probability of commercial success for ORGOVYX, MYFEMBREE or for any of our current or potential future product candidates, if approved, will depend on numerous factors, including competition, manufacturing capability and commercial viability. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

We expect our R&D expenses in fiscal year 2022 to increase as compared to fiscal year 2021, driven largely by spending on relugolix lifecycle opportunities, such as the Phase 3 SERENE study, as well as on post-marketing requirements as agreed upon with the FDA. We expect that certain R&D expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report).

Interest Expense

Our interest expense consists of related party interest expense pursuant to the Sumitomo Pharma Loan Agreement, which bears interest at a variable rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter (see Note 6(A) to our audited consolidated financial statements included elsewhere in this Annual Report), and the accretion of the financing component of the cost share advance from Pfizer (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report). Fluctuations in 3-month LIBOR could negatively impact our financial results.

Interest Income

Our interest income consists primarily of interest earned and the accretion of discounts to maturity for cash equivalents and marketable securities.

Foreign Exchange Gain

Our foreign exchange gain for the year ended March 31, 2021, consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities, relative to the U.S. dollar. The impact of foreign currency exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated liabilities. Our primary foreign currency exposure has historically been the exchange rate between the Swiss franc and the U.S. dollar.

In December 2020, we changed the functional currency of our wholly-owned subsidiary in Switzerland, MSG, from the Swiss franc to the U.S. dollar. This change in functional currency was accounted for prospectively. As a result of this change, we currently expect that future impacts of changes in foreign currency exchange rates on our results of operations will not be significant. See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report.

Results of Operations

The following table summarizes our results of operations for the years ended March 31, 2022, and 2021 (in thousands):

	Year Ended March 31,	
	2022	2021
Revenues:		
Product revenue, net	$ 94,309	$ 3,630
Pfizer collaboration revenue	104,996	22,354
Richter license and milestone revenue	31,667	33,333
Total revenues	230,972	59,317
Operating costs and expenses:		
Cost of product revenue	11,510	301
Collaboration expense to Pfizer	40,041	1,664
Selling, general and administrative	259,364	181,423
Research and development	107,403	136,713
Total operating costs and expenses	418,318	320,101
Loss from operations	(187,346)	(260,784)
Interest expense	13,971	10,401
Interest income	(384)	(211)
Foreign exchange gain	—	(16,176)
Loss before income taxes	(200,933)	(254,798)
Income tax expense	5,048	336
Net loss	$ (205,981)	$ (255,134)

Revenues

The following table provides information about our revenues for the years ended March 31, 2022, and 2021 (in thousands):

	Year Ended March 31,	
	2022	2021
Revenues:		
Product revenue, net:		
ORGOVYX	$ 82,959	$ 3,630
MYFEMBREE	6,355	—
Richter product supply and royalties	4,995	—
Total product revenue, net	94,309	3,630
Pfizer collaboration revenue:		
Amortization of upfront payment	83,897	22,354
Amortization of regulatory milestone	21,099	—
Total Pfizer collaboration revenue	104,996	22,354
Richter license and milestone revenue	31,667	33,333
Total revenues	$ 230,972	$ 59,317

We began generating product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions. There was no product revenue from sales of MYFEMBREE for the year ended March 31, 2021

For the year ended March 31, 2022, product revenue, net also includes revenues related to product supply to Richter to support their European launches of RYEQO of $4.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of $0.3 million. There were no such revenues for the year ended March 31, 2021.

Pfizer collaboration revenue for the year ended March 31, 2022, consists of the partial recognition of the upfront payment we received from Pfizer upon entering into the Pfizer Collaboration and License Agreement in December 2020 and of the regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. Pfizer collaboration revenue for the year ended March 31, 2021, consists of the partial recognition of the upfront payment received from Pfizer.

Richter license and milestone revenue for the year ended March 31, 2022 was $31.7 million, consisting of the recognition of a $15.0 million regulatory milestone payment from Richter that was triggered upon the EC approval of RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and $16.7 million of previously deferred revenue that was recognized upon the completion of our delivery of the remaining substantive relugolix combination tablet data packages to Richter. Richter license and milestone revenue for the year ended March 31, 2021, consists of the recognition of $33.3 million of the upfront and regulatory milestone payments we received from Richter in March 2020 and April 2020, respectively.

Product revenue, net by geography for the years ended March 31, 2022 and 2021 consisted of the following (in thousands):

	Year Ended March 31,	
	2022	2021
United States	$ 89,314	$ 3,630
Europe	4,995	—
Total product revenue, net	$ 94,309	$ 3,630

For the year ended March 31, 2022, compared to the year ago period, product revenue, net in the U.S. increased by $85.7 million as a result of higher ORGOVYX net revenues, as well as net revenues generated from sales of MYFEMBREE, for which there were no such MYFEMBREE net revenues for the year ended March 31, 2021.

For the year ended March 31, 2022, product revenue, net in Europe consisted of revenues related to product supply to Richter to support their European launches of RYEQO of $4.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of $0.3 million. There were no such revenues for the year ended March 31, 2021.

Cost of Product Revenue

For the year ended March 31, 2022, our cost of product revenue was $11.5 million, consisting of $4.6 million of cost of goods sold and $6.9 million of royalty expense to Takeda. For the year ended March 31, 2021, our cost of product revenue was $0.3 million, which consisted primarily of royalty expense to Takeda. The $11.2 million increase in our cost of product revenue for the year ended March 31, 2022 compared to the year ago period was due to an increase in cost of goods sold and royalty expense to Takeda as a result of higher sales of ORGOVYX during the year ended March 31, 2022, as well as sales of MYFEMBREE in the U.S., which began in the three months ended June 30, 2021, and sales of product supply to Richter that began in the three months ended September 30, 2021.

As a result of the FDA approvals of ORGOVYX and MYFEMBREE, we subsequently began capitalizing the cost of inventories manufactured or purchased for each product after its respective approval date. Previously, costs to manufacture ORGOVYX and MYFEMBREE were expensed as incurred as R&D expenses. We expect our cost of goods sold to increase in future periods as quantities of previously expensed ORGOVYX and MYFEMBREE inventories are depleted from our inventory stock.

Collaboration Expense to Pfizer

For the years ended March 31, 2022, and 2021, our collaboration expense to Pfizer was $40.0 million and $1.7 million, respectively, and represents Pfizer's 50% share of net profits from the sales of ORGOVYX and MYFEMBREE in the U.S. Collaboration expense to Pfizer increased by approximately $38.4 million for the year ended March 31, 2022, compared to the

year ago period, primarily due to an increase in net profits generated from sales of ORGOVYX in the U.S., as well as net profits generated from sales of MYFEMBREE in the U.S., for which there were no such MYFEMBREE net profits in the year ended March 31, 2021.

Selling, General and Administrative Expenses

SG&A expenses increased $77.9 million, to $259.4 million, in the year ended March 31, 2022 compared to $181.4 million in the year ago period, primarily due to higher costs related to commercial activities to support our U.S launches of ORGOVYX and MYFEMBREE. SG&A expenses are presented net of cost sharing with Pfizer pursuant to the terms of the Pfizer Collaboration and License Agreement.

The most significant components of the $77.9 million net increase in SG&A expenses include the following:

- $58.2 million increase in personnel expense primarily driven by costs associated with our commercial operations, marketing, and market access teams, and our oncology and women's health sales forces, which were hired to support our U.S. commercial launches of ORGOVYX and MYFEMBREE;
- $21.4 million increase in commercial operations expenses, net of cost sharing with Pfizer, to support our U.S. commercial launches of ORGOVYX and MYFEMBREE;
- $13.4 million increase in general overhead, administrative and information technology expenses to support our organizational growth; partially offset by
- $16.7 million decrease in shared-based compensation, as the year ended March 31, 2021 included incremental share-based compensation related to the acceleration, modification, and remeasurement of our former Principal Executive Officer's equity awards as further discussed in Note 10(H) to our audited consolidated financial statements included elsewhere in this Annual Report.

Research and Development Expenses

For the years ended March 31, 2022, and 2021, our R&D expenses consisted of the following (in thousands):

	Year Ended March 31,		
	2022	2021	Change
Program-specific costs:			
Relugolix	$ 20,549	$ 59,835	$ (39,286)
MVT-602	318	241	77
Unallocated costs:			
Personnel expenses	57,522	48,460	9,062
Share-based compensation	16,010	14,049	1,961
Other expense	13,004	14,128	(1,124)
Total R&D expenses	$ 107,403	$ 136,713	(29,310)

R&D expenses decreased $29.3 million, to $107.4 million, in the year ended March 31, 2022, compared to $136.7 million in the year ended March 31, 2021. The most significant components of the $29.3 million net decrease in R&D expenses include the following:

- $39.2 million decrease in program-specific costs related to CRO, drug supply and other study, regulatory, and manufacturing-related costs primarily due to the wind down of our Phase 3 LIBERTY, HERO and SPIRIT studies and higher cost sharing with Pfizer for certain R&D expenses in the year ended March 31, 2022. In addition, program-specific costs for the year ended March 31, 2021, include fees of approximately $5.8 million related to our initial NDA submissions for MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids and ORGOVYX for adult patients with advanced prostate cancer, which did not recur during the year ended March 31, 2022; partially offset by
- $11.0 million increase in personnel expenses and share-based compensation primarily due to an increase in medical affairs and other personnel to support the U.S. launches of ORGOVYX and MYFEMBREE.

Interest Expense

Interest expense was $14.0 million and $10.4 million for the years ended March 31, 2022, and 2021, respectively, and was primarily related to the Sumitomo Pharma Loan Agreement. Interest expense for the years ended March 31, 2022, and 2021 also includes $2.4 million and $0.6 million, respectively, of accretion of the financing component of the cost share advance from Pfizer. The increase in interest expense was primarily driven by a higher outstanding balance under the Sumitomo Pharma Loan Agreement during year ended March 31, 2022, as well as higher accretion of the financing component of the cost share advance from Pfizer, which began in the fourth quarter of the year ended March 31, 2021.

Interest Income

Interest income was approximately $0.4 million and $0.2 million for the years ended March 31, 2022, and 2021, respectively, derived from our investments in marketable securities and cash equivalents.

Foreign Exchange Gain

For the year ended March 31, 2021, we recorded a foreign exchange gain of $16.2 million, primarily as a result of the impact of fluctuations in the foreign currency exchange rate between the Swiss franc and the U.S. dollar on our outstanding balance under the Sumitomo Pharma Loan Agreement. There were no such amounts for the year ended March 31, 2022.

Income Tax Expense

Our income tax expense was $5.0 million and $0.3 million for the years ended March 31, 2022, and 2021, respectively. Our effective tax rate for the years ended March 31, 2022, and 2021 was (2.51)% and (0.13)%, respectively, and is driven by our jurisdictional earnings by location and a valuation allowance that eliminates our global net deferred tax assets. The increase in income tax expense was primarily driven by income earned by the Company's U.S. entity, Myovant Sciences, Inc.

Liquidity and Capital Resources

We have incurred losses since our inception and have an accumulated deficit of $1.25 billion as of March 31, 2022, compared to $1.05 billion as of March 31, 2021.

Sources of Liquidity

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from upfront and milestone payments we have received from Pfizer and Richter, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S. We began generating net product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively.

As of March 31, 2022, we had cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Pharma Loan Agreement of $475.5 million, consisting of $434.2 million of cash, cash equivalents, and marketable securities and $41.3 million of borrowing capacity available to us under the Sumitomo Pharma Loan Agreement. We maintain our cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. We have established guidelines relative to diversification and maturities with respect to our marketable securities to maintain safety and liquidity. Additional funds under the Sumitomo Pharma Loan Agreement may be drawn down by us no more than once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors.

We are eligible to earn additional payments from our collaboration and commercialization partners, including:

- up to $3.6 billion of additional milestone payments from Pfizer, including a regulatory milestone of $100.0 million upon the FDA approval of MYFEMBREE for endometriosis, and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. We and Pfizer equally share profits and certain expenses in the Co-Promotion Territory;

- up to $122.5 million of additional milestone payments, including regulatory milestones of up to $15.0 million and tiered sales milestones of up to $107.5 million upon reaching certain thresholds of annual net sales in Richter's Territory, and tiered royalties on net sales in Richter's Territory; and

- an upfront payment of $50.0 million from Accord, which we expect to receive in the three months ending June 30, 2022, additional commercial launch, sales-based, and other milestones totaling up to $90.5 million, and tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's territories.

Funding Requirements

We believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Annual Report. This estimate is based on our current assumptions, including assumptions related to our ability to manage our spend, that might prove to be wrong, and we could use our available capital resources sooner than we currently expect. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments, are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common shareholders' rights. The Sumitomo Pharma Loan Agreement involves, and 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, raising capital through equity offerings, making capital expenditures or declaring dividends.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase as we continue to commercialize ORGOVYX and MYFEMBREE in the U.S., prepare for additional potential regulatory approvals, initiate life cycle management activities as well as conduct post-marketing requirements as agreed upon with the FDA for our relugolix franchise, and potentially further develop our product candidates and expand our pipeline. However, while we expect our future capital requirements and operating expenses to continue to be significant, we expect our net cash burn to gradually decrease as our net product revenues increase. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of our drug products and from any product candidates that may receive marketing approval in the future;
- the achievement of regulatory milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration and license agreements;
- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for our drug products and for any product candidates that may receive marketing approval in the future;
- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, RYEQO, and any product candidates;
- costs, timing, and outcomes of regulatory submissions and regulatory reviews of our product candidates;
- costs to expand our chemistry, manufacturing, and control and other manufacturing related activities;
- costs to identify, acquire, develop, and commercialize additional product candidates;
- costs to integrate acquired technologies into a comprehensive regulatory and product development strategy;
- costs to maintain, expand, and protect our patent claims and other intellectual property rights;
- costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts;
- costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems;
- costs to service our debt obligations and associated interest payments; and
- costs to operate as a public company.

Until such time, if ever, as we can generate positive cash flows as a result of increased sales of ORGOVYX, MYFEMBREE, or any product candidate, we expect to fund our operations through a combination of cash, cash equivalents, and marketable securities currently on hand and amounts available to us under the Sumitomo Pharma Loan Agreement, subject to the consent of our board of directors, as well as potential payments we are eligible to receive from Pfizer, Richter, and Accord pursuant to the terms of our agreements with them.

Cash Flows

The following table summarizes our cash flows for the years ended March 31, 2022, and 2021 (in thousands):

	Year Ended March 31,	
	2022	2021
Net cash (used in) provided by operating activities	$ (268,559)	$ 370,628
Net cash used in investing activities	$ (18,022)	$ (9,211)
Net cash provided by financing activities	$ 25,905	$ 238,045

Operating Activities

Net cash used in operating activities was $268.6 million for the year ended March 31, 2022, and consisted of our net loss of $206.0 million (see "Results of Operations" above) and changes in operating assets and liabilities of $107.0 million (see below), partially offset by adjustments for non-cash operating items of $44.4 million. The non-cash operating items included share based compensation of $38.9 million, accretion of the implied financing component of the cost share advance from Pfizer of $2.4 million, amortization of operating lease right of use asset of $1.7 million, and depreciation expense of $1.4 million.

The changes in operating assets and liabilities included the following:

- $90.5 million decrease in cost share advance from Pfizer due to the application of shared Allowable Expenses (see Note 13(C) to our audited consolidated financial statements included elsewhere in this Annual Report);
- $30.6 million increase in amounts due to Pfizer as a result of an increase in profit share and reimbursement of Allowable Expenses incurred by Pfizer (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report);
- $21.7 million net decrease in deferred revenue as a result of the recognition of $105.0 million of Pfizer collaboration revenue and $16.7 million of Richter license and milestone revenue, partially offset by a $100.0 million regulatory milestone payment from Pfizer (see Note 13 to our audited consolidated financial statements included elsewhere in this Annual Report);
- $24.0 million increase in accrued expenses and other current liabilities, primarily driven by increases in accrued sales discounts, rebates, and allowances due to an increase in product revenue, net, accrued compensation-related expenses, and accrued royalties payable to Takeda, partially offset by a decrease in accrued R&D expenses;
- $19.7 million increase in accounts receivable, net as a result of an increase in net product revenues, mainly driven by sales of ORGOVYX in the U.S.;
- $9.0 million increase in prepaid expenses and other current assets primarily due to prepayments related to commercial manufacturing activities;
- $6.4 million increase in other assets primarily due to prepayments related to commercial manufacturing activities, partially offset by a reduction in prepaid clinical study costs;
- $5.6 million decrease in accounts payable, primarily driven by the timing of vendor invoice payments;
- $5.0 million increase in inventories, driven by the capitalization of inventory manufactured or purchased after the FDA approvals of ORGOVYX and MYFEMBREE; and
- $3.8 million net change in other operating assets and liabilities.

Net cash provided by operating activities was $370.6 million for the year ended March 31, 2021, and consisted of changes in operating assets and liabilities of $584.6 million (see below), partially offset by our net loss of $255.1 million (primarily due to our ongoing development and clinical studies, activities related to our preparation for potential regulatory approvals and commercialization of our product candidates, and the expansion of our company), adjusted for non-cash operating items of $41.2 million. The non-cash operating items included share-based compensation of $53.7 million (which included $25.7 million related to the acceleration, modification, and remeasurement of our former Principal Executive Officer's equity awards), foreign currency transaction gain of $16.2 million primarily related to the Sumitomo Pharma debt outstanding, and other items of $3.7 million.

The changes in operating assets and liabilities included the following:

- $457.9 million net increase in deferred revenue, which was driven by the upfront payment of $503.6 million received from Pfizer in December 2020 (including a $3.6 million implied financing component of a cost share advance) and a regulatory milestone payment of $10.0 million received from Richter in April 2020, partially offset by the recognition of $33.3 million of Richter license and milestone revenue and $22.4 million of Pfizer collaboration revenue (see Note 13 to our audited consolidated financial statements included elsewhere in this Annual Report);

- $121.2 million net increase in cost share advance from Pfizer, consisting of the cost share advance received from Pfizer of $150.0 million (discounted to a present value of $146.4 million), partially offset by the application of $25.2 million of shared Allowable Expenses (see Note 13(B) to our audited consolidated financial statements included elsewhere in this Annual Report);

- $15.6 million increase in accrued expenses and other current liabilities primarily due to an increase in accrued commercial and compensation-related expenses, partially offset by a decrease in accrued R&D expenses; and

- $10.1 million net change in other operating assets and liabilities primarily related to increases in accounts receivable, inventories, and prepaid expenses and other current assets, partially offset by an increase in accounts payable.

Investing Activities

For the year ended March 31, 2022, we used $18.0 million of cash in investing activities, of which $17.0 million was for the purchase of marketable securities, net of maturities, and $1.0 million was for the purchase of property and equipment.

For the year ended March 31, 2021, we used $9.2 million of cash in investing activities, of which $7.4 million was for the purchase of marketable securities, net of maturities and sales, and $1.8 million was for the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2022, $25.9 million of cash was provided by financing activities, which was primarily due to proceeds of $24.6 million from the exercise of stock options.

For the year ended March 31, 2021, $238.0 million of cash was provided by financing activities. This was primarily due to proceeds of $245.0 million borrowed under the Sumitomo Pharma Loan Agreement and proceeds of $6.7 million from the exercise of stock options, partially offset by payment of tax withholding obligations on net settlement of share awards of $13.7 million.

Contractual Obligations and Other Cash Needs

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Our most significant contractual obligations as of March 31, 2022 are summarized below.

Sumitomo Pharma Loan Agreement

We, and one of our subsidiaries, MSG, entered into a loan agreement with Sumitomo Pharma on December 27, 2019, pursuant to which Sumitomo Pharma agreed to make revolving loans to us in the aggregate principal amount of up to $400.0 million. As of March 31, 2022, the outstanding loan balance was $358.7 million and $41.3 million of borrowing capacity remains available to us, subject to the terms of the Sumitomo Pharma Loan Agreement. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the Sumitomo Pharma Loan Agreement. In addition, if Sumitomo Pharma fails to own at least a majority of our outstanding common shares, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to us, and in which case we would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Pharma Loan Agreement. See Note 6(A) to our audited consolidated financial statements included elsewhere in this Annual Report for additional information about the Sumitomo Pharma Loan Agreement.

Operating Leases

We have certain lease agreements for office space under which we are obligated to make minimum lease payments. As of March 31, 2022, we had $3.1 million of minimum lease payments due in one year and $8.4 million due over the remaining lease terms. See Note 12 to our audited consolidated financial statements included elsewhere in this Annual Report for additional information about our operating leases.

Contingent Payments

Pursuant to the Takeda License Agreement, we have committed to paying Takeda a fixed, high single-digit royalty on net sales of certain relugolix products, a low single-digit royalty on net sales of certain other relugolix products, and a high single-digit royalty on net sales of MVT-602 products in our territory, all subject to certain agreed reductions. We cannot, at this time, determine when or if royalty payments will be required or what the total amount of such payments may be. See Note 14(D) to our audited consolidated financial statements included elsewhere in this Annual Report for additional information about the Takeda License Agreement.

Contract Service Providers

In the normal course of business, we enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs, development services with respect to CROs, and other services and products for operating purposes. These agreements may include certain provisions for purchase obligations and termination obligations that could require payment for the cancellation of committed purchase obligations or for early termination of the agreements. The amounts of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreements and are considered cancellable contracts.

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 audited consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these audited consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosures of contingent liabilities. We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Management periodically reviews our estimates and makes adjustments when facts and circumstances dictate. To the extent there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. Changes in estimates and assumptions are reflected in reported results in the period in which they become known.

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the consolidated financial statements.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report, we believe the that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Under Accounting Standards Codification 606, *Revenue from Contracts with Customers*, or ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that have been determined to be within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell our products in the U.S. principally through wholesale and specialty distribution and pharmacy channels (collectively, "customers"). These customers subsequently resell our products to healthcare providers and patients. In addition to distribution agreements with customers, we enter into arrangements with healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of our products. We recognize revenue from product sales when our customer obtains control of our products, which occurs at a point in time, typically upon delivery to the customer.

We record revenues from product sales at the net sales price, or transaction 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) group purchasing organization ("GPO") discounts, performance rebates and administrative fees, (d) product returns and (e) costs of co-pay assistance programs for patients (collectively, "sales deductions"). The variability in the net transaction price for our products arises primarily from the aforementioned sales deductions. We use significant judgment in estimating certain sales deductions. 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, which would affect net product revenue and earnings in the period such variances become known.

More specifically, our significant adjustments include the following:

- *Prompt Pay Discounts*: We generally provide our customers with prompt payment discounts that are explicitly stated in the contracts and are recorded as a reduction of gross product revenues and accounts receivable in the period the related product revenue is recognized. Our provision for cash discounts was $2.4 million for the year ended March 31, 2022. A hypothetical 10% change in our cash discount provision would have had an approximate $0.2 million impact on our net revenue for the year ended March 31, 2022.

- *Product Returns*: We estimate the amount of our product sales that may be returned by our customers and record this estimate in the period the related product revenue is recognized. We estimate product return liabilities based on historical product returns, the underlying product demand, and industry specific data. Our provision for product returns was $2.9 million for the year ended March 31, 2022. A hypothetical 10% change in our product return provision would have had an approximate $0.3 million impact on our net revenue for the year ended March 31, 2022.

- *Chargebacks:* Chargebacks for discounts represent our estimated obligations resulting from contractual commitments to sell product to Public Health Service institutions, Federal government entities purchasing via the Federal Supply Schedule, GPOs, and health maintenance organizations at a discounted price. The specialty distributor, in turn, charges

back to us the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales to contracted customers. Our provision for chargebacks was $13.4 million for the year ended March 31, 2022. A hypothetical 10% change in our chargeback provision would have had an approximate $1.3 million impact on our net revenue for the year ended March 31, 2022.

- *Rebates*: Rebates consist of the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. These reserves are recorded in the same period the related revenue is recognized. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates, estimate payor mix, and expected utilization. Our estimates for expected utilization of rebates are based on historical data received from specialty pharmacies and specialty distributors since launch, as well as analog data for similar products. We monitor sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. Our liability for these rebates consists of invoices received for claims for prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for our products that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. Our provision for rebates was $33.4 million for the year ended March 31, 2022. A hypothetical 10% change in our rebate provision would have had an approximate $3.3 million impact on our net revenue for the year ended March 31, 2022.

- *Co-payment Assistance:* We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued based on actual program participation and estimates of program redemption using data provided by third-party administrators. Our provision for co-payment assistance was $5.5 million for the year ended March 31, 2022. A hypothetical 10% change in our co-payment assistance provision would have had an approximate $0.6 million impact on our net revenue for the year ended March 31, 2022.

- *Customer Fees:* We pay fees to our customers for account management, data management, and other administrative services. To the extent the services received are distinct from sales of products to the customer, we record these payments in SG&A expenses.

We have adjusted our allowances in the past based on actual experience, and we may be required to adjust these allowances and accruals in the future. The historical adjustments have not been significant to our operations. We continually monitor our allowances and accruals and make adjustments when we believe actual experience may differ from our estimates.

The following table provides a summary of activity for each significant category of discounts and allowances for the year ended March 31, 2022 (in thousands).

	Reserve - government and other incentives	Chargebacks and administrative	Returns	Sales discounts	Total
Balance as of March 31, 2021	$ 843	$ 363	$ 109	$ 79	$ 1,394
Provision related to sales in the current year	38,910	13,384	2,919	2,377	57,590
Adjustments related to prior year sales	(305)	(124)	—	—	(429)
Credits and payments made during the current year	(25,714)	(10,995)	—	(1,970)	(38,679)
Balance as of March 31, 2022	$ 13,734	$ 2,628	$ 3,028	$ 486	$ 19,876

License, Milestone, and Other Revenue

For units of account under ASC 606, we apply significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below:

- *Licenses of intellectual property*: If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees

allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, we apply judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.

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

- *Royalties and commercial milestone payments:* For arrangements that include sales-based royalties, including sales-based milestone payments based on pre-specified level of sales, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Collaboration Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. We perform this assessment throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, we first determine which units of account of the collaboration are deemed to be within the scope of ASC 808 and those that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC 606, *Revenue from Contracts with Customers*.

While ASC 808 defines collaboration arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature, such as ASC 606, or an accounting policy election by management. For units of account within collaboration arrangements that are accounted for pursuant to ASC 808, we determine an appropriate revenue recognition method and apply it consistently.

We evaluate the presentation of amounts due from our collaborative partners associated with activities in the collaborative arrangements based on the nature of each activity. We record the amounts received prior to satisfying the revenue recognition criteria as deferred revenue on our consolidated balance sheets. If we expect the related efforts underlying the deferred revenue to be satisfied within the next twelve months, we classify the deferred revenue in current liabilities, otherwise we classify it as a non-current liability.

For collaboration arrangements that are within the scope of ASC 808, the recognition of collaboration revenue (expense) requires management judgement due to the fact that the terms of collaboration arrangements may be complicated, and the nature of the collaborative activities may change over time. Management exercises judgement in determining the units of account within a collaboration arrangement and in allocating consideration to those units, estimating the collaboration revenue to be recognized, including estimating an appropriate term over which we expect the collaboration revenue to be recognized, as well as in determining the amortization method. For example, judgement is required in identifying material rights and performance obligations, and in estimating the stand-alone selling price of identified performance obligations and material rights, the estimates of which may include forecasted revenue, development timelines, discount rates and probabilities of technical and regulatory success.

There is also judgement involved in the identification of costs that we incur related to the collaboration activities, evaluating the nature of these costs (for example, whether the costs relate to a particular geography or territory or whether the costs relate to clinical or commercial activities), and applying the terms of the respective collaborative arrangement to determine the portion

of such costs that are the responsibility of the collaboration partner, which in certain circumstances requires significant judgement.

In addition, we are dependent on collaborative partners to provide us with information in a timely and accurate manner for use in preparing our consolidated financial statements and related disclosures. Certain of this information may also be subject to estimates. Should our collaborative partners fail to provide us with any such information in a timely manner, or should any estimates upon which such financial information was based, prove to be inaccurate, we could be required to record such adjustments in future periods.

Research and Development Expenses and Accruals

R&D expenses primarily include personnel-related costs for employees engaged in R&D activities and costs of third parties who conduct clinical study and clinical manufacturing activities on our behalf, and are expensed as incurred unless there is an alternative future use in other R&D projects. We expense payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product in the period incurred as R&D.

We consider regulatory approval of product candidates to be uncertain and products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, we do not capitalize the manufacturing costs for product candidates incurred prior to regulatory approval as inventory, but rather expense them as R&D expenses when incurred.

Our accruals for clinical studies and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study sites, CROs, and CMOs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price, upon achievement of a milestone event, or on a time and materials basis. Payments under these agreements depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical study or similar conditions. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, we recognize expense accruals related to clinical studies and other R&D activities based on our estimate of the degree of completion of the event or events specified in the agreements.

Our accrual estimates are dependent upon the timeliness and accuracy of data provided by third parties regarding the status and cost of studies, and may not match the actual services performed by these organizations. During the course of a clinical study, we adjust our rate of clinical study expense recognition if actual results differ from our estimates. We make estimates of our clinical study expense as of each balance sheet date based on facts and circumstances known at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and result in us reporting amounts that are too high or too low for any particular period. This could result in adjustment to our R&D expense in future periods.

Share-Based Compensation

We account for share-based compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. We measure share-based compensation cost at the grant date, based on the fair value of the award, and recognize that fair value as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures in the period in which such forfeiture occurs and record share-based compensation as though all awards are expected to vest.

We estimate the grant date fair value of stock options, and the resulting share-based compensation, using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including:

- *Expected Term.* The expected term represents the period that our share-based awards are expected to be outstanding and is determined using the simplified method in accordance with the Securities and Exchange Commission, Staff Accounting Bulletins No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).

- *Expected Volatility.* The expected volatility considers our historical volatility and the weighted average measures of volatility of a peer group of companies for a period equal to the expected term of the stock options. Our peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stages in the life cycle, or area of specialty.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for the expected term on the stock options.

- *Expected Dividend.* We have never paid, and do not anticipate paying, cash dividends on our common shares. Therefore, the expected dividend yield was assumed to be zero.

We base share-based compensation associated with restricted stock units ("RSU") and performance share units ("PSU") on the fair value of our common shares on the grant date, which equals the closing market price of our common shares on the grant date. We recognize share-based compensation related to RSUs on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We recognize share-based compensation related to PSUs if the performance criteria are deemed probable of being met. We remeasure share-based compensation liabilities at fair value each reporting period until the common share awards are settled or become mature, with the change in the fair value recorded as share-based compensation.

No tax benefits for share-based compensation have been recognized in the consolidated statements of shareholders' deficit or consolidated statements of cash flows. We have not recognized, and do not expect to recognize in the near future, any tax benefits related to share-based compensation as a result of our full valuation allowance on net deferred tax assets and net operating loss carryforwards.

Recently Issued and Adopted Accounting Pronouncements

For information regarding the impact of recently adopted accounting pronouncements and the expected impact of recently issued accounting pronouncements not yet adopted on our consolidated financial statements, see Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, as we are entitled to report as a "smaller reporting company" for this Annual Report, we are not required to provide the information otherwise required by this item in this Annual Report.

Item 8. Financial Statements and Supplementary Data

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS OF MYOVANT SCIENCES LTD.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Myovant Sciences Ltd. (the Company) as of March 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows for each of the three years in the period ended March 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of March 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated May 11, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Accounting for accrued rebates

Description of the Matter	As described in Note 2 to the consolidated financial statements, estimates for variable consideration in the determination of net product revenue are based on the amounts the Company expects to be earned or to be claimed on the related sales. The Company calculates accrued rebates based on factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, and industry data. Auditing accrued rebates is especially challenging due to the subjectivity required to estimate the accruals. Government pricing calculations used to determine the rebate price are complex and require management judgment. Claims by payers for rebates may be submitted to the Company significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. The Company adjusts its estimates based on new information, including information regarding actual rebates for its products as it becomes available.

How We Addressed the Matter in Our Audit	To test the Company's accounting for accrued rebates, our audit procedures included, among others, understanding the methodology and assumptions applied by the Company to determine the allowances for rebates. We obtained management's calculations for the respective estimates and tested management's key inputs used in the determination of accrued rebates. We assessed subsequent events to determine whether there was new information that would require adjustment to the initial accruals, evaluated trends in actual sales and accrued rebate balances, tested a sample of credits issued and payments made throughout the year, and agreed rates to underlying contract terms.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.
Redwood City, California
May 11, 2022

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Myovant Sciences Ltd.'s internal control over financial reporting as of March 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Myovant Sciences Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of March 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of March 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows for each of the three years in the period ended March 31, 2022, and the related notes and our report dated May 11, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California
May 11, 2022

MYOVANT SCIENCES LTD.
Consolidated Balance Sheets
(*in thousands, except share and per share data*)

	March 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 406,704	$ 674,493
Accounts receivable, net	23,296	3,570
Marketable securities	27,483	10,435
Inventories	7,584	2,611
Prepaid expenses and other current assets	22,498	13,536
Amount due from related party	580	—
Total current assets	488,145	704,645
Property and equipment, net	2,944	3,300
Operating lease right-of-use asset	7,961	9,655
Other assets	20,961	7,427
Total assets	$ 520,011	$ 725,027
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 12,250	$ 17,809
Accrued expenses and other current liabilities	68,594	44,612
Share-based compensation liabilities	—	21,636
Deferred revenue	100,564	100,564
Amounts due to Pfizer	32,563	1,954
Cost share advance from Pfizer	33,818	92,415
Operating lease liability	2,148	1,807
Amounts due to related parties	393	543
Total current liabilities	250,330	281,340
Deferred revenue, non-current	375,706	397,369
Cost share advance from Pfizer, non-current	—	29,447
Long-term operating lease liability	7,041	9,189
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,711	2,947
Total liabilities	993,488	1,078,992
Commitments and contingencies (Note 14)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized; 94,858,446 and 91,000,869 issued and outstanding at March 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	795,935	709,466
Accumulated other comprehensive loss	(17,285)	(17,285)
Accumulated deficit	(1,252,129)	(1,046,148)
Total shareholders' deficit	(473,477)	(353,965)
Total liabilities and shareholders' deficit	$ 520,011	$ 725,027

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

MYOVANT SCIENCES LTD.
Consolidated Statements of Operations
(*in thousands, except share and per share data*)

	Year Ended March 31,		
	2022	**2021**	**2020**
Revenues:			
Product revenue, net	$ 94,309	$ 3,630	$ —
Pfizer collaboration revenue	104,996	22,354	—
Richter license and milestone revenue	31,667	33,333	—
Total revenues	230,972	59,317	—
Operating costs and expenses:			
Cost of product revenue	11,510	301	—
Collaboration expense to Pfizer	40,041	1,664	—
Selling, general and administrative [(1)]	259,364	181,423	82,327
Research and development [(2)]	107,403	136,713	192,560
Total operating costs and expenses	418,318	320,101	274,887
Loss from operations	(187,346)	(260,784)	(274,887)
Interest expense [(3)]	13,971	10,401	12,663
Loss on extinguishment of debt	—	—	4,851
Interest income	(384)	(211)	(2,552)
Foreign exchange gain	—	(16,176)	(1,621)
Loss before income taxes	(200,933)	(254,798)	(288,228)
Income tax expense	5,048	336	761
Net loss	$ (205,981)	$ (255,134)	$ (288,989)
Net loss per common share — basic and diluted	$ (2.22)	$ (2.83)	$ (3.37)
Weighted average common shares outstanding — basic and diluted	92,974,887	90,036,459	85,839,303

[(1)] Includes $4,842 and $5,330 of related party expense (inclusive of third-party pass-through costs) for the years ended March 31, 2022 and 2021, respectively (see Note 6).

[(2)] Includes $58 of related party expense (inclusive of third-party pass-through costs) for the year ended March 31, 2021. There was no related party expense included in research and development expense for the year ended March 31, 2022 (see Note 6).

[(3)] Includes $11,551, $9,766, and $1,441 of interest expense under the Sumitomo Pharma Loan Agreement for the years ended March 31, 2022, 2021, and 2020, respectively (see Note 6).

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

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

	Year Ended March 31,		
	2022	**2021**	**2020**
Net loss	$ (205,981)	$ (255,134)	$ (288,989)
Other comprehensive loss:			
Foreign currency translation adjustment	—	(15,639)	(2,153)
Total other comprehensive loss	—	(15,639)	(2,153)
Comprehensive loss	$ (205,981)	$ (270,773)	$ (291,142)

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

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

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive (Income) Loss	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount				
Balance at March 31, 2019	72,057,490	$ 1	$ 505,851	$ 507	$ (502,025)	$ 4,334
Issuance of shares in connection with "at-the-market" equity offering, net of commissions of $79	106,494	—	2,546	—	—	2,546
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $9,292	17,424,243	1	134,457	—	—	134,458
Share-based compensation	—	—	40,102	—	—	40,102
Capital contribution from former majority shareholder — share-based compensation	—	—	149	—	—	149
Capital contribution from former majority shareholder	—	—	334	—	—	334
Foreign currency translation adjustment	—	—	—	(2,153)	—	(2,153)
Issuance of shares upon exercise of stock options and release of share awards	245,771	—	942	—	—	942
Net loss	—	—	—	—	(288,989)	(288,989)
Balance at March 31, 2020	89,833,998	2	684,381	(1,646)	(791,014)	(108,277)
Share-based compensation	—	—	53,676	—	—	53,676
Share-based compensation awards reclassified to current liabilities	—	—	(17,473)	—	—	(17,473)
Share-based compensation liabilities reclassified to equity upon settlement of awards	—	—	6,446	—	—	6,446
Share-based compensation reclassified to current liabilities	—	—	(10,609)	—	—	(10,609)
Issuance of shares upon release of share awards, net of shares withheld for taxes	261,095	—	(13,664)	—	—	(13,664)
Issuance of shares upon exercise of stock options	905,776	—	6,709	—	—	6,709
Foreign currency translation adjustment	—	—	—	(15,639)	—	(15,639)
Net loss	—	—	—	—	(255,134)	(255,134)
Balance at March 31, 2021	91,000,869	2	709,466	(17,285)	(1,046,148)	(353,965)
Share-based compensation	—	—	38,928	—	—	38,928
Share-based compensation liabilities reclassified to equity upon settlement or maturity of awards	—	—	23,335	—	—	23,335
Share-based compensation reclassified to current liabilities	—	—	(1,699)	—	—	(1,699)

Issuance of shares upon exercise of stock options and release of share awards	3,857,577	—	24,625	—	—	24,625
Capital contribution - other	—	—	1,280	—	—	1,280
Net loss	—	—	—	—	(205,981)	(205,981)
Balance at March 31, 2022	94,858,446	$ 2	$ 795,935	$ (17,285)	$ (1,252,129)	$ (473,477)

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

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

	Year Ended March 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss	$ (205,981)	$ (255,134)	$ (288,989)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Share-based compensation	38,928	53,676	40,251
Depreciation	1,378	988	673
Non-cash interest expense [1]	2,413	635	1,486
Loss on extinguishment of debt	—	—	4,851
Foreign currency transaction gain	—	(16,176)	(1,621)
Amortization of operating lease right-of-use assets	1,694	1,491	1,092
Other	10	537	(359)
Changes in operating assets and liabilities:			
Accounts receivable	(19,726)	(3,570)	—
Inventories	(4,973)	(2,611)	—
Prepaid expenses and other current assets	(8,962)	(5,267)	1,925
Amount due from related party	(580)	—	—
Income tax receivable	—	—	524
Other assets	(6,421)	(1,441)	(10)
Accounts payable	(5,617)	2,457	4,315
Interest payable	—	—	(1,077)
Accrued expenses and other current liabilities	23,982	15,552	(24,675)
Deferred revenue	(21,663)	457,933	40,000
Amounts due to Pfizer	30,609	1,954	—
Cost share advance from Pfizer	(90,457)	121,227	—
Operating lease liabilities	(1,807)	(1,516)	(882)
Deferred interest payable	—	—	(2,273)
Amounts due to related parties	(150)	528	15
Other liabilities	(1,236)	(635)	3,582
Net cash (used in) provided by operating activities	(268,559)	370,628	(221,172)
Cash flows from investing activities:			
Purchases of marketable securities	(118,748)	(63,824)	(32,076)
Maturities of marketable securities	101,700	33,261	29,240
Sales of marketable securities	—	23,125	—
Purchases of property and equipment	(974)	(1,773)	(1,099)
Net cash used in investing activities	(18,022)	(9,211)	(3,935)
Cash flows from financing activities:			
Capital contribution -other	1,280	—	—
Proceeds from issuance of common shares, net of issuance costs paid	—	—	137,004
Proceeds from related party debt financing	—	245,000	113,700
Proceeds from stock option exercises	24,625	6,709	942
Payment of tax withholding on net settlement of share awards	—	(13,664)	—
Payment of third-party debt financings and redemption and administration fees	—	—	(105,720)
Net cash provided by financing activities	25,905	238,045	145,926
Net change in cash, cash equivalents and restricted cash	(260,676)	599,462	(79,181)

Cash, cash equivalents and restricted cash, beginning of period	677,480	78,018	157,199
Cash, cash equivalents and restricted cash, end of period	$ 416,804	$ 677,480	$ 78,018
Supplemental Disclosure of Non-Cash Financing and Investing Information:			
Reclassification of share-based compensation awards from additional paid-in capital to current liabilities	$ —	$ 17,473	$ —
Change in fair value of share-based awards recorded to additional paid-in capital	$ 1,699	$ 10,609	$ —
Reclassification of share-based compensation liabilities to additional paid-in capital upon settlement or maturity of awards	$ 23,335	$ 6,446	$ —
Equipment purchases included in accounts payable	$ 58	$ 18	$ —
Supplemental Disclosure of Cash Flow Information:			
Income taxes paid	$ 3,542	$ 513	$ 38
Interest paid	$ —	$ —	$ 13,030
Interest (related party) paid	$ 11,551	$ 9,819	$ 1,426

(1) Includes imputed interest on cost share advance from Pfizer for the years ended March 31, 2022 and 2021. Includes amortization of debt discount and issuance costs for the year ended March 31, 2020.

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

Note 1—Description of Business

Myovant Sciences Ltd. (together with its wholly-owned subsidiaries, the "Company") is a biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, the Company has two FDA-approved products: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. by the U.S. Food and Drug Administration ("FDA") in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; and (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In April 2022, the EC approved ORGOVYX (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. In September 2021, the FDA accepted to review the Company's supplemental New Drug Application ("sNDA") for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. On May 6, 2022, the Company and Pfizer announced that the FDA extended the Prescription Drug User Fee Act ("PDUFA") goal date for this sNDA to August 6, 2022. MYFEMBREE is being evaluated for contraceptive efficacy in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy. The Company is also developing MVT-602, an investigational oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since its inception, the Company has funded its operations primarily from the issuance and sale of its common shares, from debt financing arrangements, and more recently from the upfront and regulatory milestone payments it has received from its collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S., and to a lesser extent from revenues generated from sales of product supply to Gedeon Richter Plc. ("Richter") as well as royalties on net sales of RYEQO in Richter's Territory.

The Company's majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma"), the name of which prior to April 1, 2022 was Sumitomo Dainippon Pharma Co., Ltd. As of March 31, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, own 50,041,181, or approximately 52.8%, of the Company's outstanding common shares.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The Company's fiscal year ends on March 31, and its first three fiscal quarters end on June 30, September 30 and December 31. The Company manages its operations as a single segment for purposes of assessing performance, making operating decisions, and allocating resources. This one operating and reporting segment primarily focuses on the development and commercialization of innovative medicines in areas of unmet medical need.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU") issued by the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Liquidity and Capital Resources

As of March 31, 2022, the Company had approximately $434.2 million in cash, cash equivalents, and marketable securities. The Company believes that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Annual Report on Form 10-K ("Annual Report").

In future periods, if the Company's cash, cash equivalents, marketable securities, and amounts that it expects to generate from product sales and/or third-party collaboration payments are not sufficient to enable the Company to fund its operations, the

Company may need to raise additional funds in the form of equity, debt, or from other sources. There can be no assurances that such funding sources will be available at terms acceptable to the Company, or at all. If the Company has insufficient funding to meet its working capital needs, it could be required to delay, limit, reduce, or terminate its drug development programs, commercialization efforts, and/or limit or cease operations.

As of March 31, 2022, the Company had approximately $41.3 million of borrowing capacity available to it under the Sumitomo Pharma Loan Agreement (see Note 6(A)). As of March 31, 2022, the Company is also eligible to earn up to $3.6 billion and $122.5 million of additional milestone payments from Pfizer and Richter pursuant to the Pfizer Collaboration and License Agreement (see Note 13(B)) and the Richter Development and Commercialization Agreement (see Note 13(A)), respectively, as well as potential royalty payments on net sales under the Richter Development and Commercialization Agreement.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the accompanying notes, and the reported amounts of revenue and expenses during the reported periods. Actual results could differ materially from those estimates.

On an ongoing basis, the Company's management evaluates its estimates, including those related to valuation of inventories, impairment testing for long-lived-assets, variables used in calculating the fair value of the Company's equity awards, expected achievement of performance-based vesting criteria for equity awards, variable consideration and other relevant inputs impacting the gross and net revenue recognition, contingent liabilities, recoverability of deferred tax assets, determination of lease term, research and development ("R&D") expenses and accruals, and effective income tax rates. Management bases estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period, that are not readily apparent from other sources. Estimates and assumptions are periodically reviewed considering changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows.

The Company has assessed the impact that the COVID-19 pandemic and the conflict in Ukraine has had on its operations and financial results as of March 31, 2022, and through May 11, 2022, the issuance date of these consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. Through May 11, 2022, the Company's results of operations and cash flows have not been significantly impacted by the COVID-19 pandemic or the conflict in Ukraine. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments, and assumptions or a revision of the carrying value of the Company's assets or liabilities as of May 11, 2022.

Reclassifications

Certain reclassifications have been made to the consolidated statements of cash flows for the years ended March 31, 2021, and 2020 to place them on a comparable basis with the year ended March 31, 2022, regarding the presentation of amortization of operating lease right-of-use assets of $1.5 million and $1.1 million, respectively. The reclassifications had no effect on the previously reported results of operations. The reclassifications had no effect on previously reported cash flows from operating activities in the consolidated statements of cash flows.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries, including, but not limited to, risks of failure or unsatisfactory results of nonclinical and clinical studies, the need for significant capital to fund the development of its product candidates and the commercialization of any product candidates that may obtain marketing approval, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of any of its product candidates that obtain regulatory approval, dependence on strategic relationships with collaboration and commercialization partners and on key personnel, securing and protecting proprietary technology, compliance with government regulations, development by competitors of technological innovations, ability to transition from pilot-scale manufacturing to large-scale production of products, and dependence on third-party service providers such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), other suppliers, and third-party logistics providers.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk include cash, cash equivalents, and marketable securities. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and the issuers of its cash equivalents and marketable securities. The Company maintains its cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities of investments to maintain safety and liquidity. The Company has not historically experienced any significant credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

The Company is also subject to credit risk from accounts receivable from product sales, amount due from its related party, and amounts due from its collaboration and commercialization partners. The Company monitors its exposure and records a reserve against uncollectible amounts as necessary.

For the year ended March 31, 2022, four customers represented 87% of the Company's ORGOVYX and MYFEMBREE product revenue, net and each of these customers represented 10% or greater of the Company's ORGOVYX and MYFEMBREE product revenue, net. As of March 31, 2022, three customers represented 82% of the Company's accounts receivable, and each of these customers represented 10% or greater of the Company's accounts receivable. For the year ended March 31, 2021, four customers represented 90% of the Company's product revenue, net and 95% of the Company's accounts receivable as of March 31, 2021, and each of these customers represented 10% or greater of the Company's product revenue, net and accounts receivable. The Company had no product sales for the year ended March 31, 2020.

Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash (maturity of three months or less at the time of purchase). Interest income consists of interest earned and the accretion of discounts to maturity for cash equivalents and marketable securities.

Restricted cash consists of funds held or designated to satisfy the requirements of certain agreements that are restricted in their use. As of March 31, 2022, and 2021, restricted cash includes approximately $7.1 million and $1.0 million, respectively, that is held in an escrow fund for use by Sunovion Pharmaceuticals Inc. ("Sunovion"), a subsidiary of Sumitomo Pharma, to manage payments for rebates, chargebacks, and similar fees pursuant to the Market Access Services Agreement (see Note 6(C)).

The following represents a reconciliation of cash and cash equivalents on the consolidated balance sheets to total cash, cash equivalents and restricted cash in the consolidated statements of cash flows (in thousands):

	March 31,		
	2022	2021	2020
Cash and cash equivalents	$ 406,704	$ 674,493	$ 76,644
Restricted cash (included in other assets)	10,100	2,987	1,374
Total cash, cash equivalents and restricted cash	$ 416,804	$ 677,480	$ 78,018

Accounts Receivable, Net

The Company's accounts receivable consists of amounts due from customers related to product sales and have standard payment terms. For certain customers, the accounts receivable for the customer is net of prompt payment discounts. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company reserves against accounts receivable for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The Company has historically not experienced significant credit losses and no amounts were reserved for estimated losses as of March 31, 2022, and 2021.

Marketable Debt Securities

Investments in marketable debt securities are held in custodial accounts at a financial institution and managed by the Company's investment advisor based on the Company's investment guidelines. The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities.

The Company classifies its marketable debt securities as available-for-sale at the time of purchase and reevaluates such designation at each balance sheet date. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are recorded in accumulated other comprehensive (loss) income until realized. Any unrealized losses are evaluated for

other-than-temporary impairment at each balance sheet date. Realized gains and losses are determined based on the specific identification method.

The Company does not intend to sell its marketable debt securities that are in an unrealized loss position, and it is unlikely that the Company will be required to sell its marketable debt securities before recovery of their amortized cost basis, which may be maturity. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the marketable debt security before recovery of the amortized cost basis. See Note 4 for additional information.

Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy contains three levels of inputs that may be used to measure fair value, in accordance with ASC 820, *Fair Value Measurement,* of which the first two are considered observable and the last is considered unobservable. These levels are as follows:

- Level 1—inputs, which include unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access;
- Level 2—inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3—inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques, as well as significant management judgment or estimation.

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

The recorded amounts of certain financial instruments, including cash, cash equivalents, accounts receivable, accounts payable, accrued liabilities, amounts due to Pfizer, and amounts due to and due from related parties, approximate fair value due to their relatively short maturities. Marketable debt securities that are classified as available-for-sale are recorded at estimated fair value and are included in Level 2 of the fair value hierarchy. The fair value of marketable debt securities is based on market prices from a variety of industry standard data providers and generally represents quoted prices for similar assets in active markets or have been derived from observable market data. Cost share advance from Pfizer is recorded at its estimated fair value and is included in Level 2 of the fair value hierarchy. Share-based compensation liabilities related to stock options are remeasured at fair value on a recurring basis using the Black-Scholes option pricing model and are included in Level 2 of the fair value hierarchy. Share-based compensation liabilities related to common shares are remeasured at fair value on a recurring basis and are included in Level 1 of the fair value hierarchy.

Inventories

The Company values its inventories at the lower-of-cost or net realizable value and determines the cost of inventories using the average-cost method. Net realizable value is the estimated selling prices in the ordinary course of the Company's business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventories is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions.

Inventories include the cost for raw materials, the cost to manufacture the raw materials into finished goods, and overhead. Due to the nature of the Company's supply chain process, inventory that is owned by the Company is physically stored at third-party warehouses, logistics providers and contract manufacturing organizations.

The Company performs an assessment of the recoverability of inventories during each reporting period and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such impairment charges are recorded as a component of cost of goods sold in the consolidated statements of operations.

The Company capitalizes inventory costs associated with products following regulatory approval when based on management's judgement, future commercialization is considered probable, and the future economic benefit is expected to be realized. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized, but rather expensed as R&D expenses when incurred.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to seven years once the asset is installed and placed into service. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized.

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

Leases

The Company determines if an arrangement includes a lease at the inception of the agreement. For each of the Company's lease arrangements, the Company records a right-of-use asset representing the Company's right to use an underlying asset for the lease term and a lease liability representing the Company's obligation to make lease payments. Operating lease right-of-use assets and operating lease liabilities are recognized at the lease commencement date based on the net present value of the remaining future minimum lease payments over the lease term. If the interest rate implicit in the Company's leases is not readily determinable, in determining the weighted-average discount rate used to calculate the net present value of lease payments, the Company utilizes an estimate of its incremental borrowing rate based on market sources including interest rates for companies with similar credit quality for agreements of similar duration, determined by class of underlying asset, to discount the lease payments. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term and variable lease costs are expensed as incurred.

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

Collaborative Arrangements

The Company may enter into collaboration arrangements with pharmaceutical and biotechnology partners. The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which units of account of the collaboration are deemed to be within the scope of ASC 808 and those that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC 606, *Revenue from Contracts with Customers*.

While ASC 808 defines collaboration arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature, such as ASC 606, or an accounting policy election by management. For units of account within collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate revenue recognition method is determined and applied consistently.

The Company evaluates the presentation of amounts due from its collaborative partners associated with activities in the collaborative arrangements based on the nature of each activity. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. If the related efforts underlying the deferred revenue are expected to be satisfied within the next twelve months, the deferred revenue is classified in current liabilities, otherwise it is classified as a non-current liability.

Revenue Recognition

For units of account under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

License, Milestone and Other Revenue

For units of account under ASC 606, the Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

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

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

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

Product Revenue, net

The Company sells its products in the U.S. principally through wholesale and specialty distribution and pharmacy channels (collectively, "customers"). These customers subsequently resell the Company's products to healthcare providers and patients. In addition to distribution agreements with customers, the Company enters into arrangements with healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products. Revenues from product sales are recognized when the customer obtains control of the Company's products, which occurs at a point in time, typically upon delivery to the customer.

Revenues from product sales are recorded at the net sales price, or "transaction 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) group purchasing organization ("GPO") discounts, performance rebates and administrative fees, (d) product returns and (e) costs of co-pay assistance programs for patients. These reserves 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, the Company utilizes 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, the Company's 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 the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts 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.

More specifically, these adjustments include the following:

- *Prompt Pay Discounts:* The Company generally provides invoice discounts on product sales to its customers for prompt payment. The Company estimates that its customers will earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

- *Product Returns*: Consistent with industry practice, the Company offers its customers limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. In arriving at its estimate for product returns, the Company considers historical product returns, the underlying product demand, and industry specific data.

- *Chargebacks:* Chargebacks are discounts that occur when contracted customers purchase directly from a specialty distributor. Contracted customers, which currently consist primarily of Public Health Service institutions, Federal government entities purchasing via the Federal Supply Schedule, GPOs, and health maintenance organizations, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back to the Company the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for chargebacks is based on actual chargebacks received and an estimate of sales to contracted customers.

- *Rebates:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates, estimated payor mix, and expected utilization. The Company's estimates for expected utilization of rebates are based on historical data received from specialty pharmacies and specialty distributors since launch, as well as analog data from similar products. The Company monitors sales trends and adjusts the allowance on a regular basis to reflect the most recent rebate experience. The Company's liability for these rebates consists of invoices received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

- *Co-payment Assistance:* The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued based on actual program participation and estimates of program redemption using data provided by third-party administrators.

- *Customer Fees:* The Company pays fees to its customers for account management, data management, and other administrative services. To the extent the services received are distinct from sales of products to the customer, the Company records these payments in Selling General and Administrative ("SG&A") expenses.

Cost of Product Revenue

Cost of product revenue is composed of the cost of goods sold and royalty expense payable to Takeda. Cost of goods sold consists of the cost of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight, and indirect overhead costs associated with sales of ORGOVYX and MYFEMBREE in the U.S. and sales of product supply to Richter. The cost of inventories written down as a result of excess, obsolescence, or other reasons is also charged to cost of goods sold. Royalty expense consists of royalties on net sales of relugolix payable to Takeda pursuant to the terms of the Takeda License Agreement (see Note 14(D)).

As a result of the FDA approvals of ORGOVYX and MYFEMBREE, the Company subsequently began capitalizing inventories manufactured or purchased for each product after its respective approval date. As a result, certain manufacturing costs of ORGOVYX and MYFEMBREE were expensed as R&D expenses prior to FDA approval and, therefore, these costs are not included in cost of goods sold.

Collaboration Expense to Pfizer

Collaboration expense to Pfizer consists of Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S. (see Note 13(B)).

Research and Development Expenses

R&D expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for employees engaged in R&D activities, expenses from third parties who conduct R&D activities on behalf of the Company, investigator grants, sponsored research, and fees incurred for regulatory submissions.

R&D costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based on an ongoing review of the level of effort and costs actually incurred. The Company expenses in-process R&D projects acquired as asset acquisitions which have not reached technological feasibility, and which have no alternative future use.

The Company considers regulatory approval of product candidates to be uncertain and products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory, but rather expensed as R&D expenses when incurred.

Promotional and Advertising Expense

Promotional and advertising costs are expensed as incurred, and are included in SG&A expenses in the consolidated statements of operations. Promotional and advertising costs consist primarily of the costs of designing, producing, and distributing materials promoting the Company's products. Certain promotional and advertising costs are shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement (see Note 13(B)).

Share-Based Compensation

The Company accounts for share-based compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. The Company's share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes forfeitures in the period in which such forfeiture occurs and records share-based compensation as though all awards are expected to vest.

The Company estimates the grant date fair value of stock options, and the resulting share-based compensation, using the Black-Scholes option-pricing model, which requires the use of subjective assumptions. These assumptions include:

- *Expected Term.* The expected term represents the period that the Company's share-based awards are expected to be outstanding and is determined using the simplified method in accordance with the Securities and Exchange Commission ("SEC"), Staff Accounting Bulletin ("SAB") No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).

- *Expected Volatility.* The expected volatility considers the Company's historical volatility and weighted average measures of volatility of a peer group of companies for a period equal to the expected term of the stock options. The Company's peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for the expected term of the stock option.

- *Expected Dividend.* The Company has never paid, and does not anticipate paying, cash dividends on its common shares. Therefore, the expected dividend yield was assumed to be zero.

The fair value of stock options on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company recognizes the expense associated with options using a single award approach over the requisite service period.

Share-based compensation associated with restricted stock units ("RSU") and performance share units ("PSU") is based on the fair value of the Company's common shares on the grant date, which equals the closing market price of the Company's common shares on the grant date. The Company recognizes the share-based compensation related to RSUs on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The Company recognizes the share-based compensation related to PSUs if the performance criteria are deemed probable of being met. Share-based compensation liabilities (a current liability) are remeasured at fair value each reporting period until the common share awards are settled or become mature, with the change in fair value recorded as share-based compensation.

No tax benefits for share-based compensation have been recognized in the consolidated statements of shareholders' deficit or consolidated statements of cash flows. The Company has not recognized, and does not expect to recognize in the near future, any tax benefits related to share-based compensation as a result of its full valuation allowance on net deferred tax assets and net operating loss carryforwards.

Income Taxes

The Company is subject to income taxes in the United States and other foreign jurisdictions. Judgment is required in determining the Company's expense (benefit) for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws.

The Company records an expense (benefit) for income taxes for the anticipated tax consequences of the reported results of operations using the asset and liability method. Under this method, the Company recognizes deferred income tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, as well as for loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. The Company recognizes the deferred income tax effects of a change in tax rates in the period of enactment.

The Company records a valuation allowance to reduce the Company's deferred tax assets to the net amount that the Company believes is more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies, and results of operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company recognizes tax benefits from uncertain tax positions if the Company believes that it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position as well as consideration of the available facts and circumstances. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense as incurred.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and potentially dilutive shares of common stock outstanding during the period. Potential dilutive securities outstanding include stock options, restricted stock units, performance stock units, and warrants. During all periods presented, the Company incurred net losses. Accordingly, the effect of any common share

equivalents would have been anti-dilutive during those periods and are not included in the calculation of diluted weighted-average number of common shares outstanding.

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per common share for the periods indicated because their inclusion would have been anti-dilutive:

	March 31,		
	2022	2021	2020
Stock options	6,130,680	8,293,331	7,723,302
Restricted stock awards (unvested)	—	—	634,623
Restricted stock units and performance stock units (unvested)	4,532,619	3,571,235	945,559
Warrants	73,710	73,710	73,710
Total	10,737,009	11,938,276	9,377,194

Change in Functional Currency

Prior to December 1, 2020, the functional currency of the Company's wholly-owned subsidiary in Switzerland, Myovant Sciences GmbH ("MSG"), was the local currency where the subsidiary is located, the Swiss franc. Transactions in foreign currencies were translated to the functional currency at the rate of exchange at the date of the transaction. Transaction gains and losses were recognized in foreign exchange (gain) loss in the consolidated statements of operations. The results of operations of MSG were translated to the U.S. dollar, the Company's reporting currency, at the average rates of exchange during the period. The cumulative effect of these exchange rate adjustments was included in a separate component of other comprehensive income (loss) on the consolidated balance sheets.

Effective December 1, 2020, as a result of significant changes in economic facts and circumstances in the operations of MSG, the functional currency of MSG was changed from the Swiss franc to the U.S. dollar. The change in the functional currency was accounted for prospectively from December 1, 2020. Therefore, any gains or losses that were previously recorded in accumulated other comprehensive income (loss) remain unchanged.

Pushdown Accounting

In November 2014, the FASB issued ASU 2014-17, *Business Combinations* (Topic 805): *Pushdown Accounting*. The ASU provides an acquired entity with an option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. An acquired entity may elect the option to apply pushdown accounting in the reporting period in which the change in control event occurs. If pushdown accounting is applied to an individual change in control event, that election is irrevocable. The Company elected not to apply pushdown accounting in its consolidated financial statements upon the change in control of the Company on December 27, 2019. See Note 6(A).

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes* (Topic 740) ("ASU 2019-12"), that eliminates certain exceptions to the general principles in ASC 740 related to intra-period tax allocation, deferred tax liability and general methodology for calculating income taxes. ASU 2019-12 also simplifies U.S. GAAP by making other changes for matters such as, franchise taxes that are partially based on income, transactions with a government that result in a step up in the tax basis of goodwill, separate financial statements of legal entities that are not subject to tax, and enacted changes in tax laws in interim periods. The Company adopted ASU 2019-12 on April 1, 2021, which did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform* (Topic 848)*: Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. These amendments apply only to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective prospectively for all entities as of March 12, 2020 through December 31, 2022. The Company's outstanding debt with Sumitomo Pharma bears a variable interest rate that is indexed off of 3-month LIBOR, for which publication is expected to be discontinued on June 30, 2023. In the event that 3-month LIBOR becomes unavailable, the Company and Sumitomo Pharma will negotiate in good faith to select an alternative interest rate in accordance with the

Sumitomo Pharma Loan Agreement. The Company has not yet adopted this guidance and is currently evaluating the potential impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326)*: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 was effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption was permitted, including adoption in any interim period. In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) *and Leases* (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amended the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company is currently assessing the impact the adoption of this new standard will have on its consolidated financial statements and related disclosures.

Note 3—Revenue Components

The following table provides information about the Company's revenues (in thousands):

	Year Ended March 31,		
	2022	2021	2020
Revenues:			
Product revenue, net:			
ORGOVYX	$ 82,959	$ 3,630	$ —
MYFEMBREE	6,355	—	—
Richter product supply and royalties	4,995	—	—
Total product revenue, net	94,309	3,630	—
Pfizer collaboration revenue:			
Amortization of upfront payment	83,897	22,354	—
Amortization of regulatory milestone	21,099	—	—
Total Pfizer collaboration revenue	104,996	22,354	—
Richter license and milestone revenue	31,667	33,333	—
Total revenues	$ 230,972	$ 59,317	$ —

Product Revenue, net

The Company began generating product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. The Company records product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

For the year ended March 31, 2022, product revenue, net also includes revenues related to product supply to Richter to support their European launches of RYEQO of $4.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of $0.3 million. There were no such revenues recorded for the years ended March 31, 2021, and 2020.

Product revenue, net by geography consisted of the following (in thousands):

	Year Ended March 31,		
	2022	2021	2020
United States	$ 89,314	$ 3,630	$ —
Europe	4,995	—	—
Total product revenue, net	$ 94,309	$ 3,630	$ —

The activities and ending balances for each significant category of discounts and allowances (which constitutes variable consideration) for the years ended March 31, 2022 and 2021 were as follows (in thousands):

	Reserve - government and other incentives	Chargebacks and administrative fees	Returns	Sales Discounts	Total
Balance as of March 31, 2020	$ —	$ —	$ —	$ —	$ —
Provision related to sales in the current year	1,351	363	109	109	1,932
Credits and payments made during the current year	(508)	—	—	(30)	(538)
Balance as of March 31, 2021	843	363	109	79	1,394
Provision related to sales in the current year	38,910	13,384	2,919	2,377	57,590
Adjustments related to prior year sales	(305)	(124)	—	—	(429)
Credits and payments made during the current year	(25,714)	(10,995)	—	(1,970)	(38,679)
Balance as of March 31, 2022	$ 13,734	$ 2,628	$ 3,028	$ 486	$ 19,876

The total reserves described above are summarized as components of the Company's consolidated balance sheets as follows (in thousands):

	March 31,	
	2022	2021
Reduction of accounts receivable, net	$ 486	$ 79
Component of accrued expenses and other current liabilities	19,390	1,315
Total revenue-related reserves	$ 19,876	$ 1,394

Pfizer Collaboration Revenue

For the year ended March 31, 2022, Pfizer collaboration revenue consists of the partial recognition of the upfront payment the Company received from Pfizer upon entering into the Pfizer Collaboration and License Agreement in December 2020 and of the regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. For the year ended March 31, 2021, Pfizer collaboration revenue consists of the partial recognition of the upfront payment the Company received from Pfizer in December 2020. There was no Pfizer collaboration revenue for the year ended March 31, 2020. See Note 13(B) for additional information regarding the Pfizer Collaboration and License Agreement.

Richter License and Milestone Revenue

Richter license and milestone revenue for the year ended March 31, 2022 was $31.7 million, consisting of the recognition of a $15.0 million regulatory milestone payment from Richter that was triggered upon the EC approval of RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and $16.7 million of previously deferred revenue that was recognized upon completion of the Company's delivery of the remaining substantive relugolix combination tablet data packages to Richter. Richter license and milestone revenue for the year ended March 31, 2021 consists of the recognition of $33.3 million of the upfront and regulatory milestone payments the Company received from Richter in March 2020 and April 2020, respectively. There was no Richter license and milestone revenue for the year ended March 31, 2020. See Note 13(A) for additional information regarding the Richter Development and Commercialization Agreement.

Note 4—Fair Value Measurements

Financial Instruments Measured at Fair Value on a Recurring Basis

The preparation of the Company's consolidated financial statements in accordance with U.S. GAAP requires that certain assets and liabilities be reflected at their fair value. The fair value of these financial instruments is based on valuations that include inputs that can be classified within one of three levels of a hierarchy established by U.S. GAAP (see Note 2). The following table summarizes the Company's assets and liabilities measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of March 31, 2022				
Assets:				
Money market funds [1]	$ 69	$ —	$ —	$ 69
Commercial paper [2]	—	219,772	—	219,772
Total assets	$ 69	$ 219,772	$ —	$ 219,841

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of March 31, 2021				
Assets:				
Money market funds [1]	$ 36,903	$ —	$ —	$ 36,903
Commercial paper [2]	—	21,689	—	21,689
U.S. agency securities [1]	—	10,000	—	10,000
Municipal bonds [3]	—	1,417	—	1,417
Total assets	$ 36,903	$ 33,106	$ —	$ 70,009
Liabilities:				
Share-based compensation liabilities - stock options [4]	$ —	$ 12,113	$ —	$ 12,113
Share-based compensation liabilities - common shares [5]	9,523	—	—	9,523
Total liabilities	$ 9,523	$ 12,113	$ —	$ 21,636

[1] Included in cash and cash equivalents.

[2] Includes $192.3 million in cash and cash equivalents and $27.5 million in marketable securities as of March 31, 2022. Includes $12.7 million in cash and cash equivalents and $9.0 million in marketable securities as of March 31, 2021.

[3] Included in marketable securities.

[4] Includes 1,281,803 outstanding stock options remeasured using the Black-Scholes option-pricing model (see Note 10(H)).

[5] Includes 462,705 common shares remeasured using the Company's March 31, 2021 closing market price of $20.58 per common share (see Note 10(H)).

The share-based compensation liabilities were remeasured at fair value at each reporting period end, with the change in fair value recorded as share-based compensation in the Company's consolidated statements of operations until the stock options were exercised and the common shares sold to Sumitovant, to the market, or otherwise settled, or the Company's former Principal Executive Officer held the common shares for a period of at least six months (see Note 10(H)). The Company remeasured the share-based compensation liabilities related to outstanding stock options at fair value using the Black-Scholes option pricing model for which all significant inputs were observable, either directly or indirectly, which caused them to be classified as a Level 2 measurement within the fair value hierarchy. The Company remeasured the share-based compensation liabilities related to common shares held for less than six months based on the closing market price of the Company's common shares at each reporting period end, which caused them to be classified as a Level 1 measurement within the fair value hierarchy.

The following table includes information regarding the Company's share-based compensation liabilities (a current liability) for the year ended March 31, 2022 and 2021 (in thousands):

	Year Ended March 31,	
	2022	2021
Balance at beginning of year	$ 21,636	$ —
Reclassification from additional paid-in capital	—	17,473
Change in fair value	1,699	10,609
Settlements	(23,335)	(6,446)
Balance at end of year	$ —	$ 21,636

The fair value of the share-based compensation liabilities related to outstanding stock options was estimated as of March 31, 2021 using the Black-Scholes option-pricing model and the following assumptions:

Expected common share price volatility	72.9 %
Expected risk free interest rate	0.06 %
Expected term, in years	0.78
Expected dividend yield	— %

There were no share-based compensation liabilities related to outstanding stock options as of March 31, 2022.

Financial Instruments Not Measured at Fair Value on a Recurring Basis

The Company recorded the cost share advance from Pfizer, which is included in Level 2 of the fair value hierarchy, at its estimated fair value of $146.4 million as of the transaction date. As discussed in Note 13(B), on the transaction date, the cost share advance from Pfizer was discounted to fair value using the Company's estimated incremental borrowing rate over the period in which the cost share advance is expected to be utilized. The recorded amount has been and will continue to be reduced each reporting period by the amount of Allowable Expenses applied to the cost share advance. There were no nonrecurring fair value assets as of March 31, 2022 and 2021.

Note 5—Certain Balance Sheet Components

Inventories

Inventories consisted of the following (in thousands):

	March 31,	
	2022	2021
Raw materials	$ 663	$ 1,390
Work in process	3,737	773
Finished goods	3,184	448
Total inventories	$ 7,584	$ 2,611

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31,	
	2022	2021
Accrued compensation-related expenses	$ 26,389	$ 20,571
Accrued sales discounts, rebates, and allowances	19,390	1,315
Accrued R&D expenses	6,955	8,544
Accrued commercial expenses	7,196	7,770
Accrued other expenses	4,029	5,014
Accrued royalties payable to Takeda	2,470	301
Accrued professional fees	1,340	935
Deferred product revenue	825	162
Total accrued expenses and other current liabilities	$ 68,594	$ 44,612

Note 6—Related Party Transactions

(A) Sumitomo Pharma

Sumitomo-Roivant Transaction

On December 27, 2019, the Company's former controlling shareholder, Roivant Sciences Ltd. ("Roivant"), completed a transaction (the "Sumitomo-Roivant Transaction") in which all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Pharma, resulting in Sumitovant directly, and Sumitomo Pharma indirectly, owning 45,008,604, or approximately 50.2%, of the Company's outstanding common shares on December 27, 2019. As of March 31, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, own 50,041,181, or approximately 52.8%, of the Company's outstanding common shares.

On December 27, 2019, the then existing Information Sharing and Cooperation Agreement between the Company and Roivant, the then existing Services Agreements between the Company and certain of its subsidiaries and Roivant and certain of its subsidiaries, and the then existing Option Agreement between the Company and Roivant were terminated. For the year ended March 31, 2020, the Company paid or reimbursed Roivant approximately $0.6 million under the terms of the then existing Services Agreements.

Sumitomo Pharma Loan Agreement

On December 27, 2019, the Company and one of its subsidiaries, MSG, entered into a Loan Agreement with Sumitomo Pharma (the "Sumitomo Pharma Loan Agreement"). Pursuant to the Sumitomo Pharma Loan Agreement, Sumitomo Pharma agreed to make revolving loans to the Company in an aggregate principal amount of up to $400.0 million. On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations of the Company to NovaQuest Capital Management ("NovaQuest") and Hercules Capital, Inc. ("Hercules") and to satisfy certain other fees and expenses (see Note 7). Funds may be drawn down by the Company once per calendar quarter, subject to certain terms and conditions, including consent of the Company's board of directors. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the Sumitomo Pharma Loan Agreement. In addition, if Sumitomo Pharma fails to own at least a majority of the outstanding common shares of the Company, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to the Company, and in which case the Company would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Pharma Loan Agreement. Loans under the Sumitomo Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Pharma Loan Agreement bear interest at a variable rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. Publication of 3-month LIBOR is currently expected to be discontinued on June 30, 2023. In the event that 3-month LIBOR becomes unavailable, the Company and Sumitomo Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate,

margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. The Company's obligations under the Sumitomo Pharma Loan Agreement are fully and unconditionally guaranteed by the Company and its subsidiaries. The loans and other obligations are senior unsecured obligations of the Company, MSG, and subsidiary guarantees. The Sumitomo Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by the Company or any of its subsidiaries and certain breaches by the Company under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Pharma may terminate its obligations to make loans to the Company and declare the principal amount of loans to become immediately due and payable, and Sumitomo Pharma may take such other actions as set forth in the Sumitomo Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Pharma to make loans to the Company would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Pharma to maintain the loans under the Sumitomo Pharma Loan Agreement or within 30 days of a change of control with respect to the Company, the Company would be required to repay the outstanding principal amount of the Loans.

As of March 31, 2022, approximately $41.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Pharma Loan Agreement, and the outstanding loan balance of $358.7 million is classified as a long-term liability on the accompanying consolidated balance sheets under the caption long-term debt, less current maturities (related party). Interest expense under the Sumitomo Pharma Loan Agreement was $11.6 million, $9.8 million, and $1.4 million for the years ended March 31, 2022, 2021, and 2020, respectively, and is included in interest expense in the accompanying consolidated statements of operations.

Annual maturities of amounts outstanding as of March 31, 2022, under the Sumitomo Pharma Loan Agreement are as follows (in thousands):

Year Ended March 31,		
2023	$	—
2024		—
2025		358,700
Total	$	358,700

Sumitomo Pharma Loan Commitment

On August 5, 2020, the Company obtained a debt commitment letter from Sumitomo Pharma, as amended by a letter dated September 29, 2020, and then further amended by a letter dated December 22, 2020 (the "2020 Commitment Letter"), pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Pharma committed to enter into a new $200.0 million unsecured, low-interest, five-year term loan facility. The 2020 Commitment Letter expired in March 2021.

Investor Rights Agreement

On December 27, 2019, the Company entered into an Investor Rights Agreement with Sumitomo Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, the Company agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, the Company agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to the Company's books, records, facilities and employees during the Company's normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for the Company's minority shareholders for so long as Sumitomo Pharma or certain of its affiliates beneficially owns more than 50% of the Company's common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of the Company's board of directors (the "board") or in the same proportion as the shareholders not affiliated with Sumitovant vote their shares; (ii) a requirement that the audit committee of the Company's board be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Pharma or certain of its

affiliates that would increase Sumitomo Pharma's beneficial ownership to over 60% of the outstanding voting power of the Company must be approved by the Company's audit committee (if occurring prior to December 27, 2022), and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares held by such shareholders; and a requirement that any related person transactions between Sumitomo Pharma or certain of its affiliates and the Company must be approved by the Company's audit committee.

Pursuant to the Investor Rights Agreement, the Company also agreed that at all times that Sumitomo Pharma beneficially owns more than 50% of the Company's common shares, Sumitomo Pharma, by purchasing common shares in the open market or from the Company in certain specified circumstances, will have the right to maintain its percentage ownership in the Company's common shares in the event of a financing event or acquisition event conducted by the Company, or specified other events, subject to specific conditions.

(B) Sumitovant

On May 18, 2020, the Company and Sumitovant entered into a consulting agreement, as amended on November 9, 2020, pursuant to which Sumitovant provided consulting services to the Company and its subsidiaries to support commercial planning, commercial launch, and implementation activities. Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of the Company's board of directors, provided services to the Company on behalf of Sumitovant under this agreement. The term of the consulting agreement with Sumitovant expired on March 31, 2021. For the year ended March 31, 2021, the Company incurred $0.8 million of expense under this consulting agreement, which is included in SG&A expenses in the accompanying consolidated statements of operations.

In addition, for the year ended March 31, 2021, the Company agreed to reimburse Sumitovant for certain other third-party pass-through expenses that it incurred on behalf of the Company. These expenses, totaling $0.7 million, are included in SG&A expense in the accompanying consolidated statements of operations. The Company reimbursed Sumitovant less than $0.1 million of third-party pass-through expenses that it incurred on behalf of the Company for the year ended March 31, 2022.

(C) Sunovion Pharmaceuticals Inc.

Market Access Services Agreement

On August 1, 2020, one of the Company's subsidiaries, MSG, entered into a Market Access Services Agreement, as amended ("Market Access Services Agreement"), with Sunovion. Pursuant to the Market Access Services Agreement, among other things, Sunovion agreed to provide to MSG certain market access services with respect to the distribution and sale of ORGOVYX ("Prostate Cancer Product") and MYFEMBREE ("Women's Health Product," and collectively with Prostate Cancer Product, the "Products", and each a "Product"), including, among other things: (i) adding the Products to Sunovion's agreements with its third party logistics providers; (ii) adding the Women's Health Product to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks and negotiating rates for the Products with certain market access customers; (iii) providing order-to-cash services; (iv) providing certain employees to provide market access account director services; (v) performing activities required in connection with supporting and maintaining contracts between the Company and market access customers for the coverage, purchase, or dispensing of the Products; (vi) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to the Products; (vii) providing MSG with price reporting metrics and other information required to allow the Company to comply with applicable government price reporting requirements; (viii) coordinating with MSG and any applicable wholesalers and distributors to address any recalls, investigations, or product holds; (ix) configuring, or causing to be configured, the appropriate software systems to enable Sunovion to perform its obligations under the Market Access Services Agreement; and (x) providing training and certain other ancillary support services to facilitate the foregoing. Pursuant to this agreement, Sunovion will also provide certain services to the Company to enable the Company to comply with its obligations under the State Transparency Laws.

MSG, in turn, appointed Sunovion as the exclusive distributor of the Women's Health Product and a non-exclusive distributor of the Prostate Cancer Product, each in the United States, including all of its territories and possessions.

In order to facilitate Sunovion's provision of these services, MSG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by MSG, solely for Sunovion's use in connection with its performance of the contemplated services; (ii) provide Sunovion periodic reports of sales projections and estimated volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which the Products will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of MSG's quality systems solely related, as reasonably determined by Myovant, to Sunovion's performance of certain regulatory services, at Sunovion's costs; and (v) promptly notify Sunovion in the event relugolix is recalled.

As consideration for the services, MSG has paid and will continue to pay Sunovion an agreed-upon monthly service charge for each of the first two years of the Market Access Services Agreement term and any agreed regulatory and training service charges. After the second year of the Market Access Services Agreement term, the monthly service charges will be determined by the parties. In addition, MSG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services, and (y) establish an escrow fund for use by Sunovion to manage payments for rebates, chargebacks and similar fees. For the years ended March 31, 2022, and 2021, the Company incurred $4.8 million and $3.8 million, respectively, under this agreement (inclusive of third-party pass-through costs billed to the Company) of which $4.8 million and $3.7 million, are included in SG&A expenses, in the accompanying consolidated statements of operations, and $0.1 million of expenses are included in R&D expenses for the year ended March 31, 2021. There were no expenses included in R&D expenses for the year ended March 31, 2022.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent not to renew the Market Access Services Agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the Market Access Services Agreement prior to the end of its term in the event of an uncured material breach by the other party, if there are certain changes of law, or if such other party becomes insolvent or undergoes a change of control. MSG may also terminate the Market Access Services Agreement with respect to one or both Products if Sunovion fails to satisfy certain market access milestones or for convenience upon payment of a break-up fee.

(D) Amended and Restated Bye-Laws

On December 22, 2019, the Company's board of directors approved, subject to the closing of the Sumitomo-Roivant transaction and shareholder approval and certain other conditions, the adoption of the Company's Fifth Amended and Restated Bye-Laws (the "New Bye-Laws"), which amended and restated the Company's bye-laws to, among other things, (i) remove the procedures established in June 2019 providing Roivant with the power, under certain circumstances, to appoint a majority of directors on the Company's board and related powers, (ii) revise certain other aspects of the Company's corporate governance and (iii) make other minor wording changes and additions, removal and revisions of defined terms. The New Bye-Laws became effective on January 23, 2020.

Note 7—Extinguishment of Debt

On December 27, 2019, the Company and one of its subsidiaries, MSG, entered into the Sumitomo Pharma Loan Agreement, which is further discussed in Note 6(A). On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations to NovaQuest and Hercules and to satisfy certain other fees and expenses, including:

- Repayment of all of the Company's then outstanding obligations to NovaQuest under the NovaQuest Securities Purchase Agreement, including $60.0 million of principal repayment of the notes, accrued and unpaid interest of $7.6 million, and an early redemption fee of $2.4 million.
- Repayment of all of the Company's then outstanding obligations to Hercules under the Hercules Loan Agreement, including $40.0 million of principal repayment of the Term Loans, accrued and unpaid interest of $0.3 million, a prepayment penalty of $0.4 million, and an end of term charge of $2.6 million.

The repayments resulted in a loss on extinguishment of debt of $4.9 million, which is included under the caption loss on extinguishment of debt in the accompanying consolidated statements of operations for the year ended March 31, 2020. The loss on extinguishment of debt was calculated as the difference between the carrying amount of the debt and the amounts paid to retire the debt.

Note 8—Income Taxes

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

	Year Ended March 31,		
	2022	2021	2020
(Loss) income before income taxes:			
United States	$ 45,446	$ (40,663)	$ (29,509)
Switzerland	(237,903)	(201,673)	(239,666)
Bermuda	(8,415)	(12,310)	(19,054)
Other[1]	(61)	(152)	1
Total loss before income taxes	$ (200,933)	$ (254,798)	$ (288,228)
Current taxes:			
United States	$ 5,048	$ 335	$ 758
Switzerland	—	—	—
Bermuda	—	1	—
Other[1]	—	—	3
Total current tax expense	5,048	336	761
Deferred taxes:			
United States	—	—	—
Switzerland	—	—	—
Bermuda	—	—	—
Other[1]	—	—	—
Total deferred tax expense	—	—	—
Total income tax expense	$ 5,048	$ 336	$ 761

[1] Primarily Ireland and United Kingdom activity.

A reconciliation of income tax expense computed at the Bermuda statutory rate to income tax expense reflected in the consolidated statements of operations is as follows (dollars in thousands):

	Year Ended March 31,					
	2022		2021		2020	
Income tax expense at Bermuda statutory rate	$ —	— %	$ —	— %	$ —	— %
Foreign rate differential[1]	(25,720)	12.80 %	(37,622)	14.77 %	(40,056)	13.90 %
Impact of changes in enacted income tax rates	—	— %	—	— %	(27,150)	9.42 %
Currency remeasurement effects on Swiss deferred tax assets	(3,045)	1.52 %	(13,742)	5.39 %	—	— %
Officer's non-deductible share-based compensation	—	— %	9,590	(3.76)%	—	— %
R&D tax credits	(2,819)	1.40 %	(3,771)	1.48 %	(1,208)	0.42 %
Share-based compensation deferral adjustment	—	— %	(4,364)	1.71 %	4,089	(1.42)%
Valuation allowance	36,331	(18.08)%	50,333	(19.75)%	65,193	(22.62)%
Other	301	(0.15)%	(88)	0.03 %	(107)	0.04 %
Total income tax expense	$ 5,048	(2.51)%	$ 336	(0.13)%	$ 761	(0.26)%

[1] Primarily related to current tax on United States operations including permanent differences as well as operations in Switzerland and the United Kingdom at rates different than the Bermuda rate.

The Company's effective tax rate for the years ended March 31, 2022, 2021, and 2020 was (2.51)%, (0.13)%, and (0.26)%, respectively, and is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets and liabilities as of March 31, 2022 and 2021 are as follows (in thousands):

	March 31,	
	2022	2021
Deferred tax assets:		
Research tax credits	$ 7,345	$ 9,967
Net operating losses	135,916	119,701
Share-based compensation	11,418	12,649
Intangibles	79,231	58,830
Lease liability	2,009	2,317
Other	10,536	7,080
Subtotal	246,455	210,544
Valuation allowance	(244,188)	(207,858)
Deferred tax assets, net of valuation allowance	2,267	2,686
Deferred tax liabilities:		
Depreciation	(526)	(651)
Right-of-use assets	(1,741)	(2,035)
Net deferred tax assets	$ —	$ —

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence, which is difficult to overcome, the Company has recorded a valuation allowance of $244.2 million and $207.9 million as of March 31, 2022 and 2021, respectively, representing the portion of the deferred tax asset that is not more likely than not to be realized. During the year ended March 31, 2022, the total change in the valuation allowance was $36.3 million, which was primarily related to certain tax attributes and intangibles. The amount of the deferred tax asset considered realizable, could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

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

As of March 31, 2022, the Company's net operating losses in Switzerland, United Kingdom and Ireland, were $987.1 million, $39.9 million, and $0.1 million, respectively. The Switzerland net operating losses will begin to expire on March 31, 2025. The net operating losses in the United Kingdom and Ireland can be carried forward indefinitely with annual usage limitations where applicable. As of March 31, 2022, the Company has R&D credit carryforwards in the United States in the amount of $5.9 million which will begin to expire on March 31, 2039 and in California in the amount of $6.1 million which can be carried forward indefinitely.

The U.S. tax attributes may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986 (the "Code"), and similar state provisions if the Company experiences one or more ownership changes, which would limit the amount of the tax attributes that can be utilized to offset future taxable income. In general, an ownership change as defined by Section 382, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation of more than 50 percentage points over a three-year period. If a change in ownership occurs in the future, the R&D credit carryforwards could be eliminated or restricted. The Company experienced an ownership change for the purposes of Section 382 and 383 of the Code in December 2019 as a result of the Sumitomo-Roivant Transaction (see Note 6(A)). Due to

the existence of the valuation allowance, limitations created by ownership changes, if any, does not materially impact the Company's effective tax rate.

The Company files income tax returns in the United Kingdom, Switzerland, Ireland, and the United States federal and certain state and local jurisdictions. The Company is subject to U.S. federal and state tax examinations for tax years ended March 31, 2019 and forward, and is subject to tax examinations in non- U.S. jurisdictions for tax years ended March 31, 2018 and forward. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the results of operations or cash flows in the period of resolution, settlement or when the statute of limitations expire.

Activity related to unrecognized tax benefits for the years ended March 31, 2022, 2021, and 2020 is as follows (in thousands):

	Year Ended March 31,		
	2022	2021	2020
Beginning of period balance	$ 4,404	$ 3,177	$ —
Gross increases — prior period tax positions	—	—	2,067
Gross decreases — prior period tax positions	(235)	(128)	—
Gross increases — current period tax positions	1,050	1,355	1,110
End of period balance	$ 5,219	$ 4,404	$ 3,177

The Company's unrecognized tax benefits increased by $0.8 million and $1.2 million for the tax years ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the Company had unrecognized tax benefits of $5.2 million that if recognized would have an immaterial effect on the Company's effective tax rate. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next twelve months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not materially impact the effective tax rate.

It is the Company's policy to recognize interest and penalties related to income tax matters in income tax expense and include accrued interest and penalties with the related income tax liability in its consolidated balance sheets. There were no interest and penalties for the years ended March 31, 2022, 2021, and 2020. As of March 31, 2022 and 2021, the Company had no accrued interest and penalties related to uncertain tax positions.

In response to the COVID-19 pandemic, many governments have enacted measures to provide aid and economic stimulus. These measures include deferring the due dates of tax payments and other changes to income and non-income-based-tax laws as well as providing direct government assistance through grants and forgivable loans. On March 27, 2020, the U.S. Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic and the negative impacts that it had on the global economy and U.S. companies. The CARES Act includes measures to assist companies, including temporary changes to income and non-income-based tax laws. The Company implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020.

As of March 31, 2022, the Company has deferred $0.9 million of employer payroll taxes, which is included in accrued expenses and other current liabilities on the consolidated balance sheet. As of March 31, 2021, the Company had deferred $1.8 million of employer payroll taxes, of which $0.9 million was included in accrued expenses and other current liabilities and $0.9 million was included in other liabilities on the consolidated balance sheet.

Note 9—Shareholders' Deficit

(A) Overview

The Company's Memorandum of Association, filed on February 2, 2016 in Bermuda, authorized the creation of one class of shares. As of March 31, 2022, the Company had 564,111,242 shares authorized with a par value of $0.000017727 per share.

(B) Underwritten Public Equity Offering of Common Shares

On June 4, 2019, the Company completed an underwritten public equity offering of 17,424,243 of its common shares at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs paid by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the exercise of the underwriters' option to purchase additional common shares, were approximately $134.5 million.

The Company's former majority shareholder, Roivant, purchased 2,424,242 of the Company's common shares in the Company's June 4, 2019 underwritten public equity offering at the same price offered to the public of $8.25 per common share, for a total purchase price of $20.0 million.

(C) At-the-Market Equity Offering Program

In April 2018, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), to sell its common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acted as the Company's agent. During the year ended March 31, 2020, the Company issued and sold 106,494 of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $24.65 per common share for aggregate net proceeds to the Company of approximately $2.5 million after deducting underwriting commissions and offering costs paid by the Company. No shares were sold under the Sales Agreement during the year ended March 31, 2021. The "at-the-market" equity offering program expired in March 2021.

(D) Warrants

As of March 31, 2022 and 2021, warrants exercisable for an aggregate of 49,800 of the Company's common shares (exercise price of $15.06 per common share) and warrants exercisable for an aggregate of 23,910 of the Company's common shares (exercise price of $18.82 per common share), were outstanding and exercisable. The warrants may be exercised on a cashless basis through October 2024 and March 2025, respectively.

Note 10—Share-Based Compensation

The Company has two share-based compensation plans, the Myovant Sciences Ltd. 2020 Inducement Plan and the Myovant Sciences Ltd. 2016 Equity Incentive Plan (collectively, the "Equity Plans").

(A) 2020 Inducement Plan

In November 2020, the compensation committee of the Company's board of directors adopted the Myovant Sciences Ltd. 2020 Inducement Plan (the "2020 Inducement Plan"), which, subject to the adjustment provisions thereof, reserved 1.0 million shares of the Company's common shares for issuance. The 2020 Inducement Plan was adopted without shareholder approval pursuant to the Listed Company Manual Rule 303A.08 ("Rule 303A.08") of the New York Stock Exchange (the "NYSE"). The 2020 Inducement Plan provides for the grant of restricted stock units and non-qualified stock options, and contains terms and conditions intended to comply with the inducement award exception under the NYSE rules. In accordance with Rule 303A.08, awards under the 2020 Inducement Plan may only be made to individuals not previously employees of the Company, or being rehired following a bona fide period of interruption of employment, as an inducement material to such individuals' entering into employment with the Company. An award is a right to receive the Company's common shares pursuant to the 2020 Inducement Plan pursuant to a restricted stock unit award or a non-qualified stock option award. On March 22, 2022, the compensation committee of the Company's board of directors adopted the first amendment to the 2020 Inducement Plan, which, subject to the adjustment provisions thereof, increased the authorized shares of the Company's common shares for issuance from 1.0 million to 2.0 million under the 2020 Inducement Plan. All of the other terms of the 2020 Inducement Plan remained the same. As of March 31, 2022, there were 1.0 million common shares available for future issuance under the 2020 Inducement Plan.

(B) 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, as amended (the "2016 Plan"), under which 4.5 million common shares were originally reserved for issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of common shares reserved for issuance under the 2016 Plan automatically increases on April 1 of each year, commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On April 1, 2021, the number of common shares authorized for issuance under the 2016 Plan increased automatically by 3.6 million shares in accordance with the evergreen provision. As of March 31, 2022, a total of 2.6 million common shares were available for future issuance under the 2016 Plan.

The Company's employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other share awards under the 2016 Plan.

(C) Stock Option Repricing

On August 26, 2019 (the "repricing date"), the Company's board of directors approved a stock option repricing program (the "repricing") whereby certain previously granted and still outstanding vested and unvested stock options held by current employees and certain executives were repriced on a one-for-one basis to $7.78 per share, which represented the closing market

price of the Company's common shares on the repricing date. To be eligible to participate in the stock option repricing program, 735,428 vested stock options to certain executives as of the repricing date were subject to a one-year exercise restriction period beginning from the repricing date. No other terms of the repriced stock options were modified, and the repriced stock options retained their original vesting schedules and expiration dates. As a result of the repricing, 5,095,013 vested and unvested stock options outstanding on the repricing date with original exercise prices ranging from $8.82 to $24.44, and a median exercise price of $17.28 per share, were repriced under this program. The repricing resulted in one-time incremental stock-based compensation expense of $9.2 million, which is being recognized over the remaining term of the repriced stock options.

(D) Stock Options

Each non-qualified stock option has an exercise price equal to the fair market value of the Company's common shares on the date of grant. Stock options granted to employees generally vest over a four-year period. One fourth of the shares subject to such stock options vest on the first anniversary of the grant date, with the balance of the shares vesting in twelve equal quarterly installments thereafter. Initial stock options granted to non-executive members of the Company's board of directors vest over a three-year period. One third of the shares subject to such stock options vest on the first anniversary of the grant date, with the balance of the shares vesting in eight equal quarterly installments thereafter. The vesting of stock options is subject to in each case to continued service through each of the vesting dates.

Annual stock options granted to non-executive members of the Company's board of directors vest in full on the earlier to occur of (i) the first (1st) anniversary of the date of grant and (ii) the day immediately prior to the date of the annual general meeting of shareholders for the year following the year in which the grant is made, subject in each case to continued service through the vesting date.

Each non-qualified stock option award has a maximum term of 10 years from the date of grant, subject to the earlier cancellation prior to vesting upon cessation of service to the Company. Options that are forfeited or expire are available for future grants.

Activity for stock options for the year ended March 31, 2022 is included in the following table:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2021	8,293,331	$ 9.90	6.48	$ 90,699
Granted	1,178,625	$ 18.93		
Exercised	(2,513,887)	$ 9.80		
Forfeited	(827,389)	$ 17.07		
Options outstanding at March 31, 2022	6,130,680	$ 10.71	6.98	$ 26,467
Options vested and expected to vest at March 31, 2022	6,130,680	$ 10.71	6.98	$ 26,467
Options exercisable at March 31, 2022	3,754,020	$ 8.41	6.08	$ 20,978

The aggregate intrinsic value of stock options is calculated as the pre-tax difference between the weighted-average exercise price of the stock options and the closing price per share of the Company's common shares of $13.32 and $20.58 on March 31, 2022 and 2021, respectively. The calculation excludes any stock options with an exercise price higher than the closing price of the Company's common shares.

As of March 31, 2022, 2021, and 2020, there were 3,754,020, 5,219,403, and 3,009,080 vested stock options outstanding, respectively.

The Company estimated the fair value of each stock option on the date of grant using the Black-Scholes option-pricing model applying the weighted average assumptions in the following table:

	Year Ended March 31,		
	2022	2021	2020
Expected common share price volatility	71.9 %	75.7 %	69.5 %
Expected risk free interest rate	1.03 %	0.47 %	2.05 %
Expected term, in years	6.2	6.21	6.17
Expected dividend yield	— %	— %	— %

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

	Year Ended March 31,		
	2022	2021	2020
Intrinsic value of options exercised	$ 23,305	$ 12,154	$ 1,036
Grant date fair value of options vested	$ 37,326	$ 19,923	$ 2,112
Weighted-average grant date fair value per share of options granted	$ 12.12	$ 7.22	$ 11.54

(E) Restricted Stock Awards and Restricted Stock Units

Restricted stock units ("RSU") and Restricted Stock Awards ("RSA") are share awards that, upon vesting, will deliver to the holder shares of the Company's common shares. RSUs generally vest over a four-year period. Activity for RSUs for the year ended March 31, 2022 is included in the following table:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested balance at March 31, 2021	3,194,562	$ 12.68
Granted	3,376,403	$ 18.21
Vested	(1,220,572)	$ 11.92
Forfeited	(964,426)	$ 15.17
Unvested balance at March 31, 2022	4,385,967	$ 16.60

The total fair value of RSUs vested during the years ended March 31, 2022, 2021, and 2020 was $14.5 million, $3.3 million and $0.2 million, respectively. The total fair value of RSAs vested during the years ended March 31, 2021 and 2020 was $8.4 million and $1.4 million, respectively. No RSAs vested during the year ended March 31, 2022.

(F) Performance Share Units

Activity for performance share units ("PSU") for the year ended March 31, 2022 is included in the following table:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested balance at March 31, 2021	376,673	$ 7.99
Granted	—	$ —
Vested	(123,118)	$ 7.87
Forfeited	(106,903)	$ 8.08
Unvested balance at March 31, 2022	146,652	$ 8.04

The vesting of PSUs requires that certain performance conditions are achieved during the performance period and is subject to the employee's continued service requirements. The total fair value of PSUs vested during the years ended March 31, 2022, 2021, and 2020 was $1.0 million, $3.6 million, and $0.8 million, respectively.

(G) Share-Based Compensation

Share-based compensation was as follows (in thousands):

	Year Ended March 31,		
	2022	2021	2020
Share-based compensation recognized as:			
SG&A expense	$ 22,918	$ 39,627	$ 25,727
R&D expense	16,010	14,049	14,524
Total	$ 38,928	$ 53,676	$ 40,251

Share-based compensation capitalized to inventories was not material during the year ended March 31, 2022. There was no share-based compensation capitalized to inventories for the years ended March 31, 2021 and 2020.

Total unrecognized share-based compensation was approximately $83.0 million as of March 31, 2022 and is expected to be

recognized over a weighted-average period of approximately 2.8 years.

Share based compensation included in SG&A for the year ended March 31, 2022 includes $1.7 million related to the settlement and remeasurement of the Company's former Principal Executive Officer's equity awards (see Note 10(H)) and $1.3 million of expense related to the accelerated vesting and modification of the post-termination exercise period of the Company's former Principal Financial Accounting Officer's equity awards (see Note 10(I)).

Share-based compensation included in SG&A expense for the year ended March 31, 2021 includes $25.7 million of incremental expense as a result of the separation of the Company's former Principal Executive Officer (see Note 10(H)).

Share-based compensation included in SG&A and R&D expense for the year ended March 31, 2020 includes $10.2 million and $1.8 million, respectively, related to the accelerated vesting of certain share-based payment awards as a result of the change in control of the Company described in Note 6(A).

(H) Separation Agreement with Former Principal Executive Officer

In January 2021, the Company entered into a Separation and General Release Agreement with its former Principal Executive Officer. Pursuant to the terms of this agreement, all of the former Principal Executive Officer's then outstanding and unvested equity awards became fully vested. In addition, the post-termination period during which the former Principal Executive Officer could exercise her outstanding stock options was extended to 12 months. The former Principal Executive Officer granted Sumitovant or any Sumitovant affiliate a right of first refusal to purchase her common shares of the Company under certain circumstances and provide the Company and its affiliates a general release of claims.

As a result of the repurchase feature described above, the outstanding awards were reclassified from additional paid-in capital to current liabilities. The share-based compensation liabilities were remeasured at fair value each reporting period end, with the change in fair value recorded as share-based compensation within SG&A expense until the stock options were exercised and the common shares sold to Sumitovant, to the market, or otherwise settled, or the former Principal Executive Officer held the common shares for a period of at least six months. As of March 31, 2021, $21.6 million is included in share-based compensation liabilities on the consolidated balance sheet. The former Principal Executive Officer's outstanding stock options were exercisable through January 11, 2022. On January 11, 2022, 331,265 stock options were canceled and the remaining share-based compensation liability was reclassified to additional paid-in capital.

(I) Separation Agreement with Former Principal Financial and Accounting Officer

In August 2021, the Company entered into a Separation Agreement and General Release with its former Principal Financial and Accounting Officer. Pursuant to the terms of this agreement, 25% of the former Principal Financial and Accounting Officer's then outstanding and unvested equity awards became fully vested. In addition, the post-termination period during which he could exercise his outstanding stock options was extended to six months.

Note 11—Defined Contribution Plan

The Company sponsors a defined contribution plan pursuant to Section 401(k) of the U.S. Internal Revenue Code that allows eligible participating employees to contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the Internal Revenue Code. Beginning in February 2020, the Company implemented a discretionary employer matching contribution of $0.50 for every $1.00 contributed by a participating employee up to 6% of the employee's eligible compensation, which such matching contributions becoming fully vested immediately. For the years ended March 31, 2022, 2021, and 2020, the Company recorded total expense for matching contributions of $3.0 million, $1.6 million, and $0.2 million, respectively.

Note 12—Leases

The Company adopted ASU 2016-2, *Leases*, (Topic 842) as of April 1, 2019 on a modified retrospective basis and did not restate comparative periods as permitted under the transition guidance. The Company elected the practical expedient not to apply the recognition and measurement guidance of Topic 842 to short-term leases.

The Company leases 40,232 square feet of office space located in Brisbane, California pursuant to a lease agreement, as amended, that expires in May 2026. The Company has the option to extend the lease term for an additional seven years but is not reasonably certain that it will exercise the option and has therefore excluded it from the lease term. The lease agreement, as amended, required the Company to deliver an irrevocable standby letter of credit in the amount of $0.5 million to the landlord, the amount of which is subject to reduction to approximately $0.2 million if certain conditions are met.

The Company subleases an additional 20,116 square feet of office space within the same building as its current corporate office space located in Brisbane, California. The sublease term expires in February 2024. The sublease required the Company to deliver an irrevocable standby letter of credit to the sublessor for the duration of the lease in the amount of $0.2 million.

In June 2020, the Company entered into an agreement to lease fleet vehicles along with certain services whereby the Company leases vehicles to be delivered by the lessor from time to time with various monthly costs depending on the vehicles delivered for a term of one year, commencing on each corresponding delivery date. The Company maintains a letter of credit of $1.2 million as collateral in favor of the lessor. The Company recognizes vehicle lease payments as expense in the consolidated statements of operations on a straight-line basis over the lease term and variable lease payments are recognized as they occur in the consolidated statements of operations.

The Company has no other significant operating, financing, or short-term leases.

The Company recognizes rent expense on a straight-line basis over the non-cancelable term of its operating leases. The components of operating lease and short-term lease expenses were as follows (in thousands):

	Year Ended March 31,		
	2022	2021	2020
Operating lease cost	$ 2,914	$ 2,914	$ 2,496
Short-term lease cost	1,710	5	—
Variable lease cost [1]	1,171	538	225
Total operating lease cost	$ 5,795	$ 3,457	$ 2,721

[1] Variable lease cost includes common area maintenance and utilities costs that are not included in operating lease liabilities and are expensed as incurred, and maintenance and one-time charges related to the short-term leases.

Certain information related to the Company's operating lease right-of-use assets and operating lease liabilities was as follows (in thousands):

	Year Ended March 31,		
	2022	2021	2020
Cash paid for operating lease liabilities	$ 3,028	$ 2,939	$ 2,289
Operating lease right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ —	$ 12,237

As of March 31, 2022, the Company's operating leases had a weighted average remaining lease term of 3.8 years and a weighted average discount rate of 12.3%.

As of March 31, 2022, maturities of operating lease liabilities were as follows (in thousands):

Years Ended March 31,	
2023	$ 3,127
2024	3,053
2025	2,409
2026	2,482
Thereafter	416
Total lease payments	11,487
Less imputed interest [1]	(2,298)
Present value of future minimum lease payments	9,189
Less operating lease liability, current portion	(2,148)
Operating lease liability, long-term portion	$ 7,041

[1] The Company's lease agreements do not provide an implicit rate. The imputed interest was determined using the Company's incremental borrowing rate, which represents an estimated rate of interest that it would have to pay to borrow equivalent funds on a collateralized basis over a similar term at the lease inception date.

Note 13—Collaboration and License Agreements

(A) Richter Development and Commercialization Agreement

On March 30, 2020, one of the Company's subsidiaries, MSG, entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand (the "Richter Development and Commercialization Agreement"). Under the terms of the Richter Development and Commercialization Agreement, the Company received an upfront payment of $40.0 million on March 31, 2020, is eligible to receive up to $40.0 million in regulatory milestone payments (of which $25.0 million has been received), $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval.

Under the terms of the Richter Development and Commercialization Agreement, the Company continues to lead global development of relugolix combination tablet. The Company also agreed to assist Richter in transferring manufacturing technology from the Company's CMOs to Richter to enable Richter to manufacture relugolix combination tablet. The Company agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company's agreements with its CMOs. Richter is responsible for local clinical development, manufacturing, and all commercialization activities for its territories. The Company has also granted Richter an option to collaborate with the Company on relugolix combination tablet for future indications in women's health other than fertility.

The Company determined that the transaction price under the Richter Development and Commercialization Agreement totaled $50.0 million, consisting of the upfront payment of $40.0 million received on March 31, 2020 and a $10.0 million regulatory milestone payment received in April 2020. No other regulatory milestones, sales-related milestones, or royalties on net sales following regulatory approval were included in the transaction price given the substantial uncertainty related to their achievement. The Company concluded that Richter represented a customer and applied relevant guidance from ASC 606. The Company identified one material combined performance obligation to grant a license to Richter to certain of its intellectual property and to deliver certain clinical and regulatory data packages for relugolix combination tablet, the drug used for both potential indications of uterine fibroids and endometriosis. The Company determined that its grant of a license to Richter to certain of its intellectual property was not distinct from the delivery of certain clinical and regulatory data packages pertaining to relugolix combination tablet. In evaluating the appropriate measure for the Company's performance under the combined performance obligation, the Company determined that revenues should be recognized as data packages are delivered to Richter based on the relative value of the data packages delivered to date compared to the totality of the data packages it is obligated to deliver under the Richter Development and Commercialization Agreement. The Company evaluated the measure of progress each reporting period and, if necessary, adjusted the measure of performance and related revenue recognition. Based upon the Company's assessment of its progress toward delivering relugolix combination tablet clinical and regulatory data packages to Richter, the Company concluded that as of March 31, 2021, it had satisfied approximately two-thirds of the combined performance obligation and recognized $33.3 million of the transaction price as Richter license and milestone revenue during the year ended March 31, 2021. The Company recognized the remaining $16.7 million of the transaction price as Richter license and milestone revenue during the year ended March 31, 2022, as the Company completed delivery of the remaining substantive relugolix combination tablet data packages to Richter. There was no such revenue recognized in the year ended March 31, 2020.

On July 16, 2021, the EC approved RYEQO as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This approval triggered a $15.0 million regulatory milestone payment from Richter, which the Company recorded as Richter license and milestone revenue during the year ended March 31, 2022.

The term of the Richter Development and Commercialization Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Richter Development and Commercialization Agreement) for the respective product in a country in the Richter Territory. The Richter Development and Commercialization Agreement may be terminated in its entirety or on a country-by-country basis by mutual consent of the parties, or by either party for the uncured material breach of the other party, for bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Richter Development and Commercialization Agreement.

(B) Pfizer Collaboration and License Agreement

On December 26, 2020, one of the Company's subsidiaries, MSG, and Pfizer, entered into a collaboration and license agreement (the "Pfizer Collaboration and License Agreement"), pursuant to which the Company and Pfizer collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). In addition, Pfizer also received an option to acquire exclusive commercialization and development rights to

relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries (the "Pfizer Territory"). Pfizer notified the Company on October 22, 2021 of its decision to decline this option.

In the Co-Promotion Territory, the Company and Pfizer equally share profits and certain expenses, including certain pre-launch inventory costs incurred by the Company prior to the effective date of the Pfizer Collaboration and License Agreement (the "Allowable Expenses"). The Company remains responsible for regulatory interactions and drug supply and continues to lead clinical development for MYFEMBREE in the women's health indications, while development for ORGOVYX is shared equally among the parties.

In the U.S., the Company is the principal on all sales transactions with third parties and recognizes 100% of product sales to third parties as revenue from contracts with customers. The Company concluded that based on the principal versus agent guidance in ASC 606, it has primary responsibility for fulfilling customer orders, controls inventory before it is sold to third party customers, assumes the risk of inventory loss, and maintains discretion in establishing product price.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company received an upfront payment of $650.0 million in December 2020, and is eligible to receive up to $3.8 billion of milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for MYFEMBREE in uterine fibroids and endometriosis ($200.0 million in the aggregate), and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. In July 2021, the Company received a $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company has and will continue to bear Pfizer's share of Allowable Expenses, up to a maximum of $100.0 million for calendar year 2021 and up to a maximum of $50.0 million for calendar year 2022. Any unused portion will carry over into the subsequent calendar years until the Company has assumed in aggregate $150.0 million of Pfizer's share of the Allowable Expenses.

The term of the Pfizer Collaboration and License Agreement continues until no products are sold and all development activities have terminated in the Co-Promotion Territory. The Pfizer Collaboration and License Agreement may be terminated early by either party for the uncured material breach of the other party or for bankruptcy or other insolvency proceeding of the other party. In addition, Pfizer has certain other termination rights and may terminate the Pfizer Collaboration and License Agreement early upon providing written notice to the Company pursuant to the terms of the Pfizer Collaboration and License Agreement.

The Company assessed the Pfizer Collaboration and License Agreement and determined that it meets both criteria to be considered a collaborative agreement within the scope of ASC 808: active participation by both parties and exposures to significant risks and rewards dependent on the commercial success of the activities. Although the Company is lead party and will perform many activities, both development and commercialization responsibilities are assigned between parties and both parties participate on joint steering and other committees overseeing the collaboration activities. Both parties are exposed to significant risks and rewards based on the economic outcomes of the collaboration through cost sharing and profit (loss) sharing provisions. Net payments to/from Pfizer for Pfizer's share of the net profits and Allowable Expenses will be disaggregated and presented in the Company's consolidated statements of operations according to the nature of the expense (e.g., collaboration expense, R&D expenses, or SG&A expenses).

As discussed above, the Company received a $650.0 million upfront payment from Pfizer in December 30, 2020, of which $150.0 million is Pfizer's advanced reimbursement for Pfizer's share of Allowable Expenses (up to $100.0 million for calendar year 2021 and up to $50.0 million for calendar year 2022). The Company concluded that the prepayment by Pfizer of its share of Allowable Expenses represents a significant financing component since the Company received the cash flows at the outset of the arrangement, rather than over a two-year period. Accordingly, the Company reduced the amount of the advanced reimbursement by approximately $3.6 million, representing the implied financing costs based on the Company's incremental borrowing rate that was derived based on the Sumitomo Pharma Loan Agreement, and recorded the discounted value of $146.4 million on the consolidated balance sheet as a deposit liability (cost share advance from Pfizer) as of the transaction date, split between a current and a non-current portion, based on the expected timing of Allowable Expenses subject to cost share. The financing component has been and will continue to be accreted to interest expense utilizing a method that approximates the effective yield method over the period in which the cost share advance is expected to be used. The remainder of the upfront payment was recorded as deferred revenue and has been and will continue to be recognized as Pfizer collaboration revenue on a straight-line basis over the estimated term of the agreement of six years, which was estimated by the Company based upon the terms of the Pfizer Collaboration and License Agreement, including the termination provisions contained therein. The Company determined straight-line amortization to be appropriate because the upfront payment represents payment for Pfizer's right to participate in the collaboration activities, including both commercialization and development activities, which are expected to be realized evenly over this period.

The achievement of regulatory milestones is outside of the Company's control and therefore was not deemed probable at contract inception. Amounts associated with the regulatory milestones were not initially recognized. Upon achievement of the related regulatory milestones, cumulative catch-up revenue will be recorded as Pfizer collaboration revenue in the period in which the respective regulatory milestone is achieved, and the remainder will be recognized over the remaining contract term. The Company determined that, conceptually, the regulatory milestone payments represent payment for development activities that will continue to benefit the collaboration as the products move toward commercialization. Accordingly, the recognition of revenue associated with the regulatory milestones follows the same amortization model as the upfront payment described above.

Similar to the regulatory milestones, sales-based milestone payments will not initially be recognized due to the uncertainty associated with the future commercial outcomes of ORGOVYX and MYFEMBREE. Upon achievement, the sales-based milestones will be recognized as revenue immediately in the period when the annual sales thresholds are met as the payments represent consideration for past activities that are completed and culminated in the annual sales thresholds being met.

The amount due to Pfizer as of March 31, 2022 was approximately $32.6 million and consisted of $14.1 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX and MYFEMBREE in the U.S. and approximately $18.5 million for 50% of Pfizer's reimbursement of Allowable Expenses. 100% of all expenses related to Pfizer under the Pfizer Collaboration and License Agreement are initially expensed and then the full pool of expenses incurred by both the Company and Pfizer are reduced through application of the cost sharing allowance.

The amounts due to Pfizer as of March 31, 2021 was approximately $1.9 million and consisted of $1.8 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX in the U.S. and approximately $0.1 million of Pfizer's reimbursement of Allowable Expenses.

The Company determined that the option exercise fee associated with Pfizer's option to acquire exclusive commercialization and development rights to relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries, did not give rise to a material right since the option fee, coupled with the net royalty payments, reflected its standalone selling price. As such, no separate accounting was required with respect to the option at contract inception. Pfizer notified the Company on October 22, 2021 of its decision to decline this option.

(C) Contract Balances

The Company records contract liabilities when cash payments are received or due in advance of the Company's performance pursuant to license and collaboration agreements. The Company's contract liabilities consist of deferred revenue and a cost share advance from its collaboration partner, Pfizer.

The following table presents changes in the Company's contract liabilities during the years ended March 31, 2022 and 2021 (in thousands):

	Balance at March 31, 2021	Additions	Imputed Interest	Deductions	Balance at March 31, 2022
Contract liabilities:					
Deferred revenue[1]	$ 497,933	$ 100,000	$ —	$ (121,663)	$ 476,270
Cost share advance from Pfizer[2]	$ 121,862	$ —	$ 2,413	$ (90,457)	$ 33,818

	Balance at March 31, 2020	Additions	Imputed Interest	Deductions	Balance at March 31, 2021
Contract liabilities:					
Deferred revenue[1]	$ 40,000	$ 513,620	$ —	$ (55,687)	$ 497,933
Cost share advance from Pfizer[2]	$ —	$ 146,384	$ 635	$ (25,157)	$ 121,862

(1) Includes $100.6 million and $375.7 million presented as current and non-current, respectively, on the consolidated balance sheet as of March 31, 2022. Includes $100.6 million and $397.4 million presented as current and non-current, respectively, on the consolidated balance sheet as of March 31, 2021.

(2) Includes $33.8 million presented as current on the consolidated balance sheet as of March 31, 2022. Includes $92.4 million and $29.4 million presented as current and non-current, respectively, on the consolidated balance sheet as of March 31, 2021.

The Company had no contract assets as of March 31, 2022 and 2021.

During the year ended March 31, 2022, deferred revenue decreased by $21.7 million. The net decrease was the result of the recognition of $105.0 million of Pfizer collaboration revenue and $16.7 million of Richter license and milestone revenue, partially offset by a $100.0 million regulatory milestone from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021.

During the year ended March 31, 2021, deferred revenue increased by $457.9 million. The increase was the net result of a $503.6 million upfront payment received from Pfizer and a $10.0 million regulatory milestone payment received from Richter, partially offset by the recognition of $33.3 million of license and milestone revenue related to the Richter Development and Commercialization Agreement and the recognition of $22.4 million of collaboration revenue related to the Pfizer Collaboration and License Agreement.

During the year ended March 31, 2022, cost share advance from Pfizer decreased by $88.0 million. The decrease was the net result of the application of 100% of shared Allowable Expenses incurred by the Company and 50% of reimbursement of Allowable Expenses incurred by Pfizer of approximately $90.4 million (consisting of $30.7 million and $59.7 million in reductions to R&D expenses and SG&A expenses, respectively), partially offset by accretion of the implied financing component of $2.4 million.

During the year ended March 31, 2021, cost share advance from Pfizer increased by $121.9 million. The increase was the net result of the cost share advance of $150.0 million (discounted to a present value of $146.4 million) received from Pfizer, partially offset by the application of 100% shared Allowable Expenses incurred by the Company and 50% of reimbursement of Allowable Expenses incurred by Pfizer of $25.2 million (consisting of $14.1 million and $11.1 million in reductions to R&D expenses and SG&A expenses, respectively), and the accretion of the implied financing component of $0.6 million.

Note 14—Commitments and Contingencies

(A) Legal Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. For cases in which the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the loss contingency, including an estimable range, if possible. The Company is currently not involved in any material legal proceedings.

(B) Contract Service Providers

In the normal course of business, the Company enters into agreements with contract service providers to assist in the performance of its R&D and clinical and commercial manufacturing activities. Subject to required notice periods and the Company's obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, clinical and commercial manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(C) Indemnification Agreements

The Company has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director was serving at the Company's request in such capacity. The maximum amount of potential future indemnification liability is unlimited; however, the Company holds directors' and officers' liability insurance which limits the Company's exposure and may enable it to recover a portion of any future amounts paid. In the normal course of business, the Company also enters into contracts and agreements with service providers and other parties with which it conducts business that contain indemnification provisions pursuant to which the Company has agreed to indemnify the party against certain types of third-party claims. The Company has agreed to indemnify Sumitomo Pharma against certain losses, claims, liabilities and related expenses incurred by Sumitomo Pharma, subject to the terms of the Sumitomo Pharma Loan Agreement and the

Investor Rights Agreement. The Company has also agreed to indemnify Sunovion against certain losses, claims, liabilities and related expenses incurred by Sunovion, subject to the terms of the Market Access Services Agreement, as amended. The Company has not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related accruals have been established.

(D) Takeda Agreements

On April 29, 2016, Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted the Company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. Pursuant to the license agreement (the "Takeda License Agreement"), Takeda granted to the Company an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. Under the Takeda License Agreement, the Company will pay Takeda a fixed, high single-digit royalty on net sales of certain relugolix products, a low single-digit royalty on net sales of certain other relugolix products, and a high single-digit royalty on net sales of MVT-602 products in the Company's territory, all subject to certain agreed reductions. For the years ended March 31, 2022 and 2021, the Company recorded royalty expense to Takeda of $6.9 million and $0.3 million, respectively, which is included in cost of product revenue on the consolidated statements of operations. No amounts were recorded in the year ended March 31, 2020. As of March 31, 2022 and 2021, the Company recorded royalties payable to Takeda of $2.5 million and $0.3 million, respectively, which are included in the accrued expenses and other current liabilities on the consolidated balance sheets. Takeda will pay the Company a high single-digit royalty on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones.

If the Takeda License Agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by the Company for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then the Company must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed upon cap, or complete by itself the conduct of any clinical studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

In May 2018, the Company entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which Takeda agreed to supply the Company and the Company agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications.

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018 and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement will automatically renew for successive one-year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

Note 15—Subsequent Event

On May 5, 2022, one of the Company's subsidiaries, MSG, entered into an exclusive license agreement (the "Accord License Agreement") with Accord Healthcare, Ltd. ("Accord") and Intas Pharmaceuticals, Ltd., parent entity of Accord, for Accord to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX® (relugolix 120 mg) in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if the Company decides to enter into licensing arrangements in countries in the Middle East, Africa, and India.

Under the terms of the Accord License Agreement, the Company is entitled to receive an upfront payment of $50.0 million, which it expects to receive in the three months ending June 30, 2022. The Company is also eligible to receive up to $90.5 million in commercial launch, sales-based, and other milestones, as well as tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's territories.

Under the terms of the Accord License Agreement, the Company retains all rights to relugolix in the U.S. with its collaboration partner, Pfizer, as well as rights to relugolix in other therapeutic areas outside of prostate cancer, uterine fibroids, and endometriosis in Europe. The Company will continue to lead the global development of relugolix and provide initial product supply to Accord. Accord will be responsible for certain local clinical development and all commercialization for its territories, and has the option to manufacture relugolix in the future.

The term of the Accord License Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Accord License Agreement). The Accord License Agreement may be terminated in its entirety or on a country-by-country basis by either party for the uncured material breach or bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Accord License Agreement.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

(1) Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(2) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for Myovant Sciences, Ltd. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2022. In making this assessment, our management used the criteria in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO). Based on its assessment, our management, including our principal executive officer and principal financial officer, has concluded that, as of March 31, 2022, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of our internal control over financial reporting as of March 31, 2022, as stated in their attestation report which is included herein.

(3) Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fiscal quarter ended March 31, 2022, that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III.

We intend to file a definitive proxy statement for our 2022 Annual General Meeting of Shareholders ("2022 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after March 31, 2022. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2022 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in our 2022 Proxy Statement under the captions "Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers" and, if applicable, "Delinquent Section 16(a) Reports" and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be contained in our 2022 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Executive Compensation" and "Director Compensation" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be contained in our 2022 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be contained in our 2022 Proxy Statement under the captions "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in our 2022 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm, Appointment of Auditor for Statutory Purposes and Authorization for the Board to Set Auditor Remuneration" and is incorporated herein by reference.

PART IV. FINANCIAL INFORMATION

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements. Our audited consolidated financial statements and the Report of Independent Registered Public Accounting Firm are included herein on the pages indicated:

(2) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or the required information is included in the audited consolidated financial statements or notes thereto.

(3) Exhibits.

Exhibit Index

Exhibit No.		Description of Document	Schedule / Form	File No.	Exhibit No.	Filing Date
3.1		Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2		Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3		Fifth Amended and Restated Bye-Laws.	10-Q	001-37929	3.3	02/10/2020
4.1		Description of Common Shares.	10-K	001-37929	4.1	05/18/2020
4.2		See Exhibits 3.1 - 3.3.				
10.1		Letter Agreement, dated October 31, 2019, by and between the Registrant and Sumitomo Dainippon Pharma Co., Ltd.	10-Q	001-37929	10.1	02/10/2020
10.2		Loan Agreement, dated as of December 27, 2019, by and among Sumitomo Dainippon Pharma Co., Ltd., as the Lender, the Registrant, as the Parent, and Myovant Sciences GmbH, as the Borrower.	10-Q	001-37929	10.2	02/10/2020
10.3		Investor Rights Agreement, dated as of December 27, 2019, by and among the Registrant, Sumitovant Biopharma Ltd. and Sumitomo Dainippon Pharma Co., Ltd.	10-Q	001-37929	10.3	02/10/2020
10.4	*	License Agreement, dated April 29, 2016, by and between the Registrant and Takeda Pharmaceuticals International AG and Amendment No. 1 dated August 30, 2016.	10-K	001-37929	10.4	05/18/2020
10.5	*	Amendment No. 2 to License Agreement, effective as of November 19, 2019, by and between the Registrant and Takeda Pharmaceuticals International AG.	10-K	001-37929	10.5	05/18/2020
10.6	*	Amendment No. 3 to License Agreement, effective as of December 15, 2020, by and between the Registrant and Takeda Pharmaceuticals International AG.	10-Q	001-37929	10.2	02/11/2021
10.7	†*	Amendment No. 4 to License Agreement, dated March 24, 2022, by and between the Registrant and Takeda Pharmaceuticals International AG.				
10.8	*	Agreement for the Manufacture and Supply of Clinical Trial Material, dated June 7, 2016, by and between the Registrant and Takeda Pharmaceuticals Company Limited, as amended.	10-K	001-37929	10.6	05/18/2020
10.9	*	Commercial Manufacturing & Supply Agreement, effective as of May 30, 2018, by and between Myovant Sciences GmbH and Takeda Pharmaceutical Company Limited.	10-K	001-37929	10.13	05/11/2021
10.10	*	Commercial Manufacturing and Supply Agreement, dated April 4, 2019, by and between Excella GmbH & Co. KG and Myovant Sciences GmbH.	10-Q	001-37929	10.2	11/12/2020
10.11	*	Market Access Services Agreement, dated as of August 1, 2020, by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH.	10-Q	001-37929	10.1	11/12/2020
10.12	*	Amendment No.1 to Market Access Services Agreement, dated as of December 14, 2020, by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH.	10-Q	001-37929	10.4	02/11/2021

10.13	*	Amendment No.2 to Market Access Services Agreement, dated as of January 25, 2021, by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH.	10-K	001-37929	10.17	05/11/2021
10.14	*	Collaboration and License Agreement, dated December 26, 2020, by and between Myovant Sciences GmbH and Pfizer Inc.	10-Q	001-37929	10.5	02/11/2021
10.15	*	Letter Agreement, dated May 4, 2021, by and between Myovant Sciences GmbH and Pfizer Inc.	10-Q	001-37929	10.2	07/28/2021
10.16	*	Letter Agreement, dated July 27, 2021, by and between Myovant Sciences GmbH and Pfizer, Inc.	10-Q	001-37929	10.3	10/26/2021
10.17	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Frank Karbe and Myovant Sciences, Inc.	10-Q	001-37929	10.2	11/08/2018
10.18	+	Separation Agreement and General Release, dated as of August 11, 2021, by and between Frank Karbe and Myovant Sciences, Inc.	10-Q	001-37929	10.2	10/26/2021
10.19	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Matt Lang and Myovant Sciences, Inc.	10-Q	001-37929	10.3	11/08/2018
10.20	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Juan Camilo Arjona Ferreira, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.4	11/08/2018
10.21	+	Employment Agreement, dated as of January 4, 2021, by and between David Marek and Myovant Sciences, Inc.	10-K	001-37929	10.25	05/11/2021
10.22	+	Employment Agreement, effective as of April 5, 2021, by and between Lauren Merendino and Myovant Sciences, Inc.	10-K	001-37929	10.27	05/11/2021
10.23	+	Employment Agreement, dated as of August 12, 2021, by and between Uneek Mehra and Myovant Sciences, Inc.	10-Q	001-37929	10.1	10/26/2021
10.24	+	Form of Indemnification Agreement with directors and executive officers.	S-1	333-213891	10.8	09/30/2016
10.25	+	2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.5	10/20/2016
10.26	+	Forms of Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.6	09/30/2016
10.27	+	Form of Amendment No.1 to the Stock Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	10-Q	001-37929	10.1	11/12/2019
10.28	+	Form of Early Exercise Stock Purchase Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.7	09/30/2016
10.29	+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended.	10-K	001-37929	10.30	05/24/2019
10.30	+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended (2019 U.S. Form).	10-Q	001-37929	10.2	11/12/2019
10.31	+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended (2019 Non-U.S. Form).	10-K	001-37929	10.35	05/11/2021

10.32	+	Form of Restricted Stock Award Agreement under 2016 Equity Incentive Plan, as amended.	10-K	001-37929	10.31	05/24/2019
10.33	+	2020 Inducement Plan.	10-Q	001-37929	10.5	11/12/2020
10.34	+	Amendment No.1 to 2020 Inducement Plan	8-K	001-37929	10.1	03/25/2022
10.35	+	Form of Option Grant Notice and Option Agreement under 2020 Inducement Plan.	10-Q	001-37929	10.6	11/12/2020
10.36	+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2020 Inducement Plan (U.S. Form).	10-Q	001-37929	10.7	11/12/2020
10.37	+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2020 Inducement Plan (Non-U.S. Form).	10-K	001-37929	10.40	05/11/2021
10.38	+	2020 Incentive Bonus Arrangements with Executive Officers.	10-Q	001-37929	Part II -Item 5	02/10/2020
10.39	+	Form of 2021 Incentive Bonus Letter with Executive Officers.	10-K	001-37929	10.42	05/11/2021
10.40	†+	Non-Executive Director Compensation Policy				
21.1	†	Subsidiaries of the Registrant.				
23.1	†	Consent of independent registered public accounting firm.				
31.1	†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1	††**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2	††**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS		Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH		Inline XBRL Taxonomy Extension Schema				
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase				
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase				
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase				
104		Cover Page Interactive Data File- the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				

† Filed herewith.

†† Furnished herewith.

+ Indicates management contract or compensatory plan.

* Portions of this exhibit have been omitted from this exhibit (indicated by asterisks) as such portions are both (a) not material and (b) would likely cause competitive harm to the Registrant if publicly disclosed, or is the type of information that the Registrant treats as private or confidential.

** These certifications are being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MYOVANT SCIENCES LTD.

By: /s/ David Marek

David Marek
(Principal Executive Officer and Director)

Date: May 11, 2022

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Marek and Uneek Mehra, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Myovant Sciences Ltd., and any or all amendments (including post-effective amendments) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ David Marek David Marek	Principal Executive Officer and Director (Principal Executive Officer)	May 11, 2022
/s/ Uneek Mehra Uneek Mehra	Principal Financial Officer (Principal Financial and Accounting Officer)	May 11, 2022
/s/ Myrtle Potter Myrtle Potter	Chairman and Director	May 11, 2022
/s/ Terrie Curran Terrie Curran	Director	May 11, 2022
/s/ Mark Guinan Mark Guinan	Director	May 11, 2022
/s/ Adele Gulfo Adele Gulfo	Director	May 11, 2022
/s/ Hiroshi Nomura Hiroshi Nomura	Director	May 11, 2022
/s/ Nancy Valente Nancy Valente	Director	May 11, 2022

[This page intentionally left blank]

[This page intentionally left blank]